US007842053B2

(12) **United States Patent**
Chanduszko et al.

(10) **Patent No.: US 7,842,053 B2**
(45) **Date of Patent: Nov. 30, 2010**

(54) **DOUBLE COIL OCCLUDER**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 314 days.

(21) Appl. No.: **11/093,348**

(22) Filed: **Mar. 30, 2005**

(65) **Prior Publication Data**

US 2005/0251154 A1 Nov. 10, 2005

Related U.S. Application Data

(60) Provisional application No. 60/568,526, filed on May 6, 2004.

(51) **Int. Cl.**
A61B 17/08 (2006.01)

(52) **U.S. Cl.** **606/157**

(58) **Field of Classification Search** 606/215, 606/139, 151, 157, 159, 213, 232; 623/3.1
See application file for complete search history.

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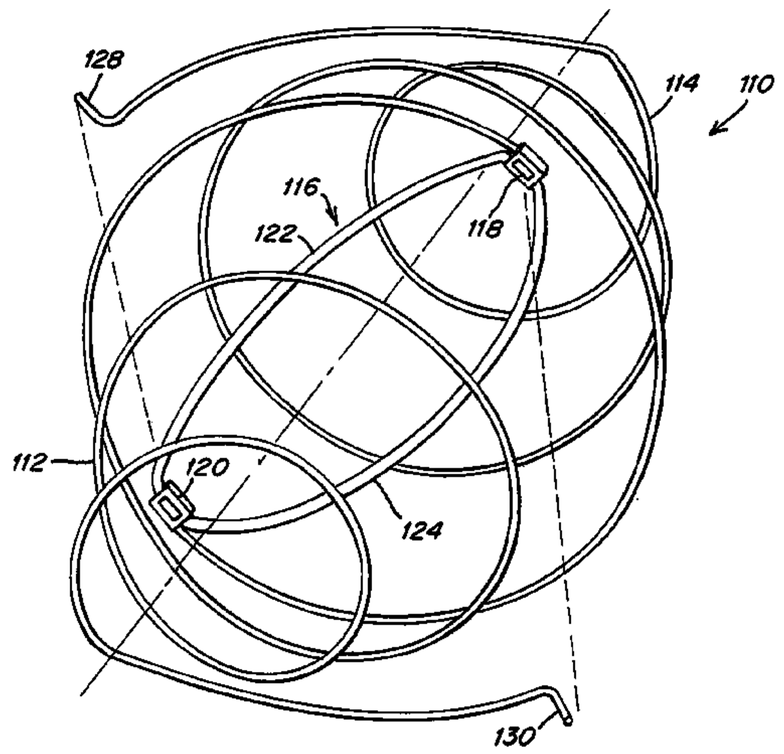
(57) **ABSTRACT**

An occluder that has a coil on one or both sides of a medical defect, particularly a septal defect such as a patent foramen ovale (PFO). Each coil can be formed as a tube that is hollow, with or without a closed end. The tube can be delivered over a wire. For occluding a PFO, the coils can be designed to provide a compressive force to one or both of septum primum and septum secundum.

25 Claims, 14 Drawing Sheets



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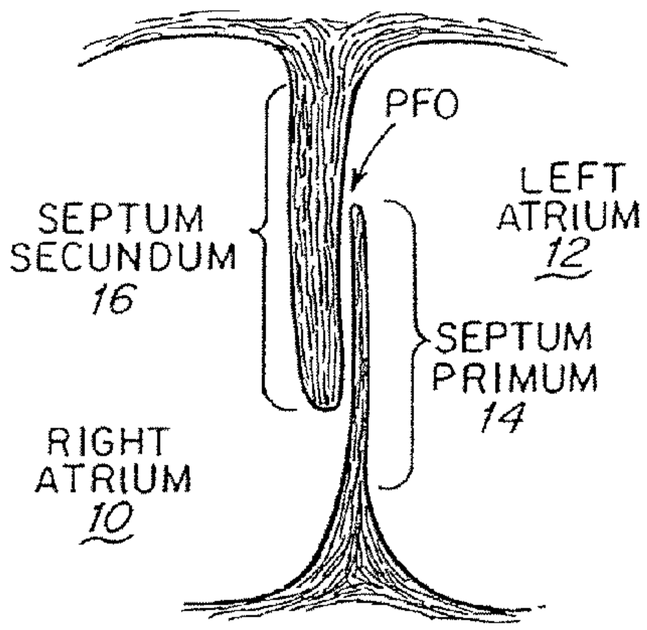


Fig. 1

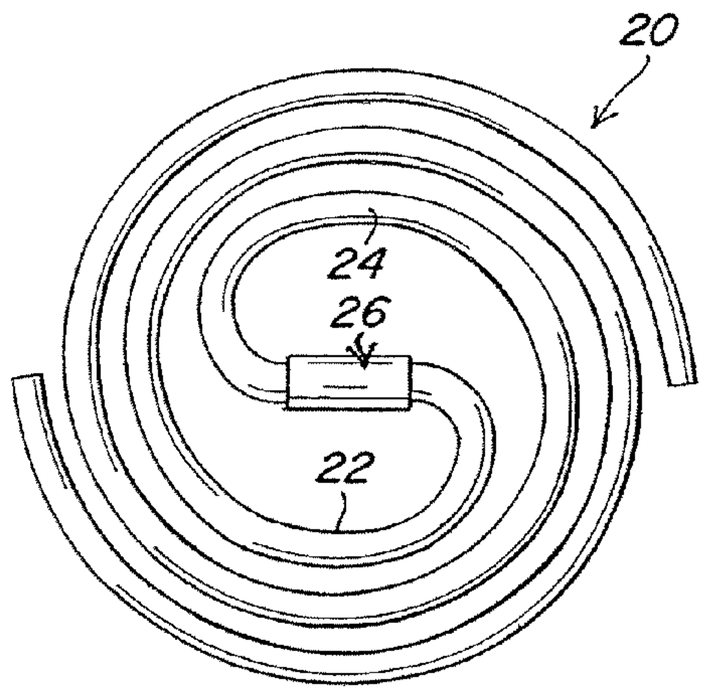


Fig. 2A

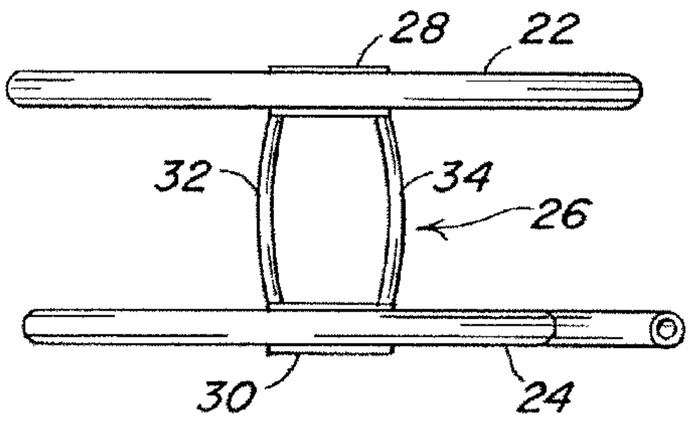


Fig. 2B

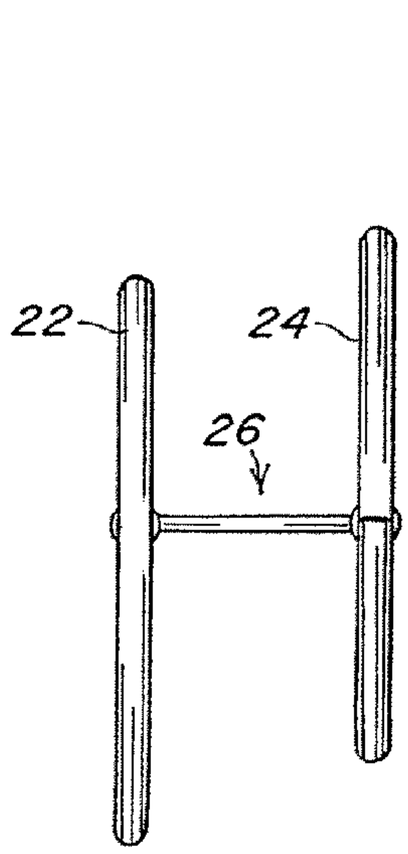


Fig. 3A

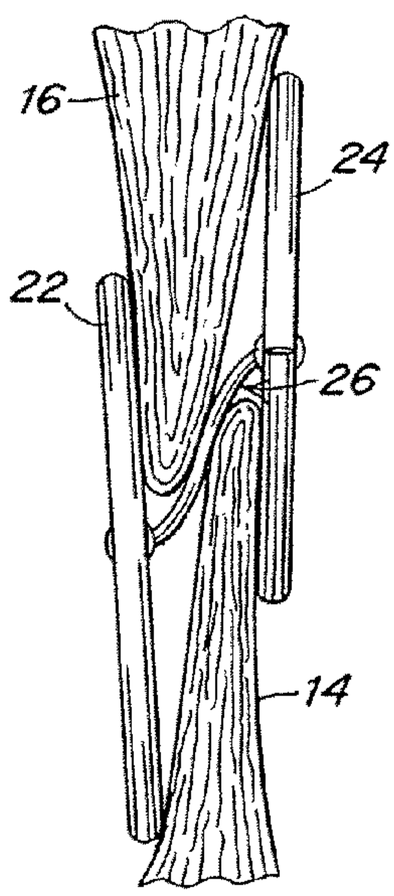
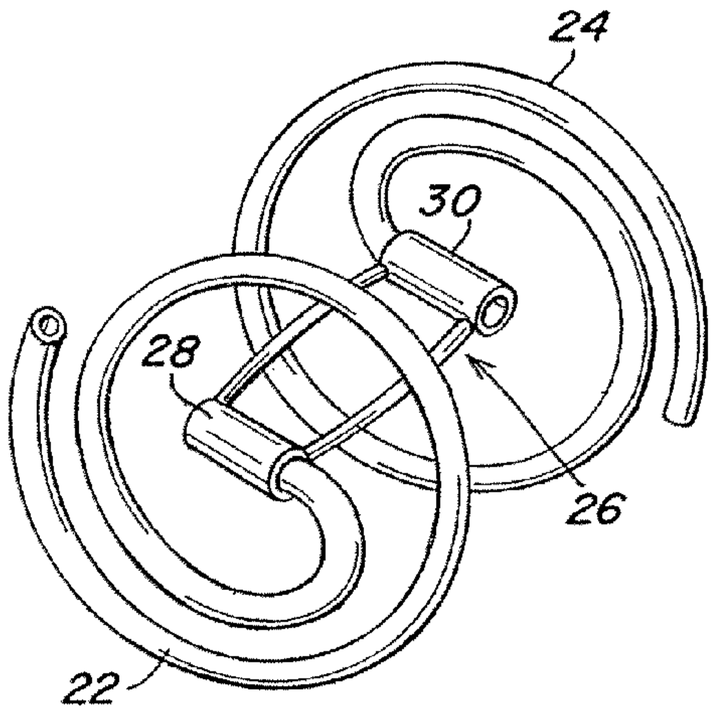


Fig. 3B



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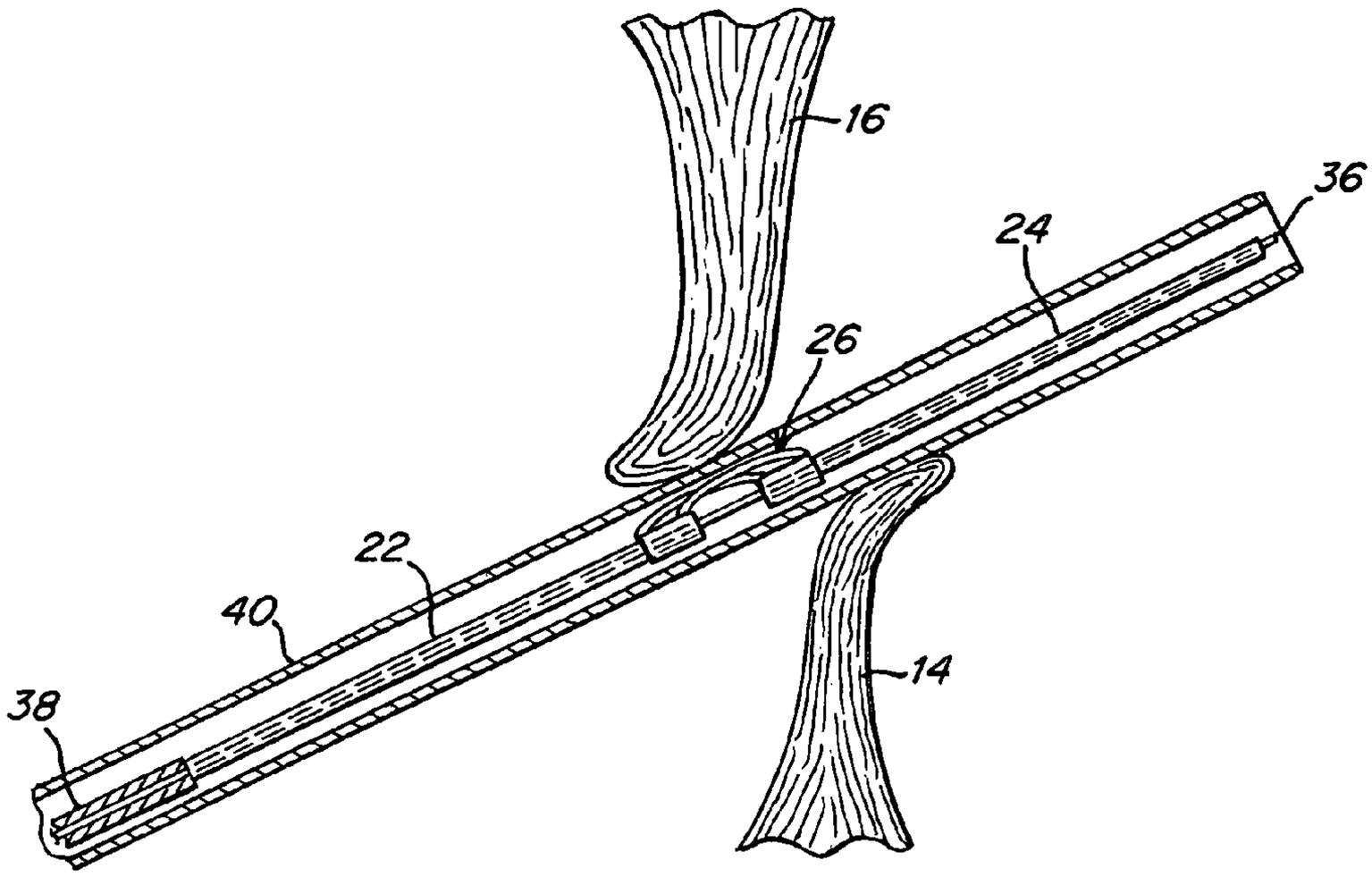

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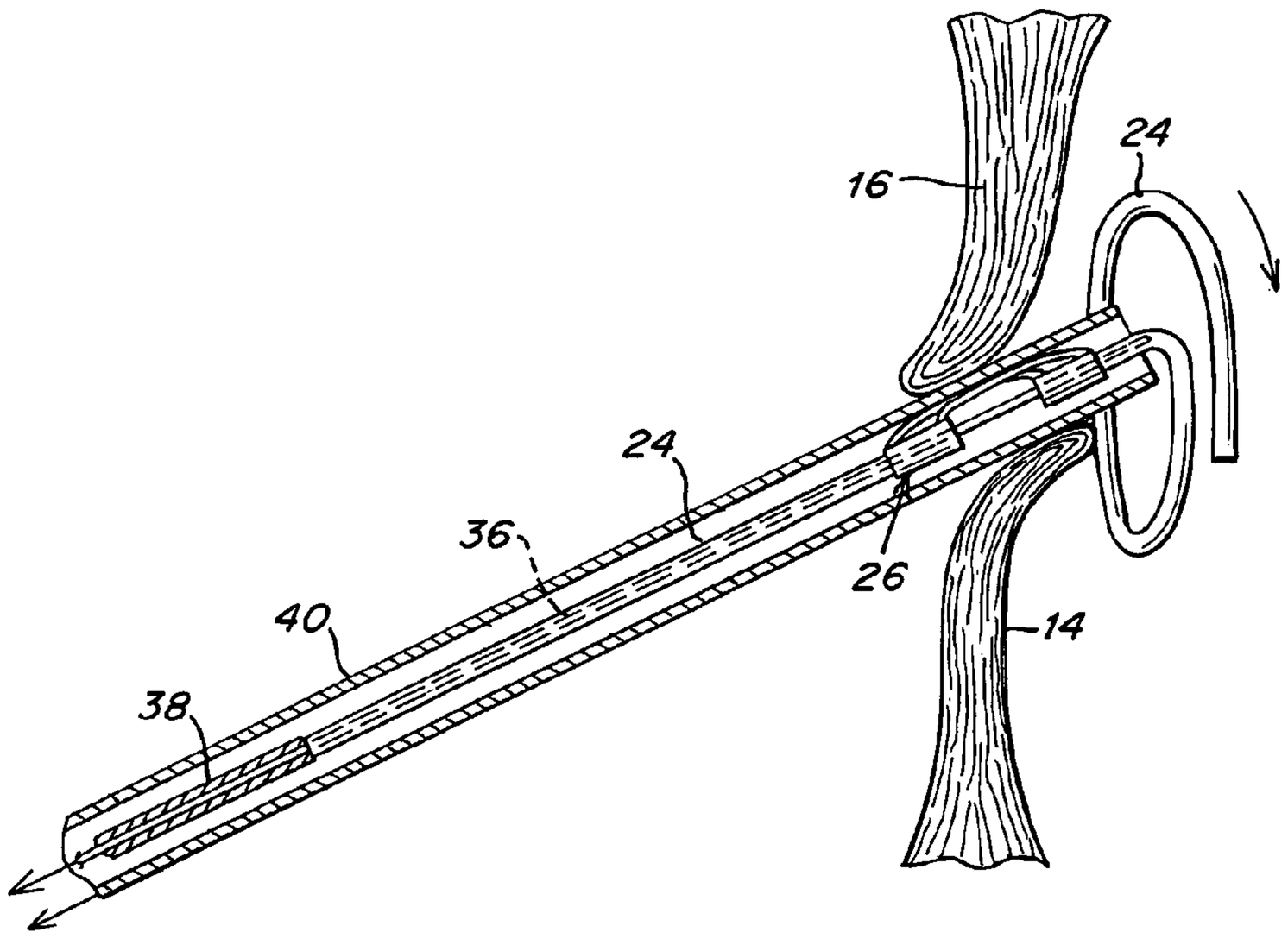

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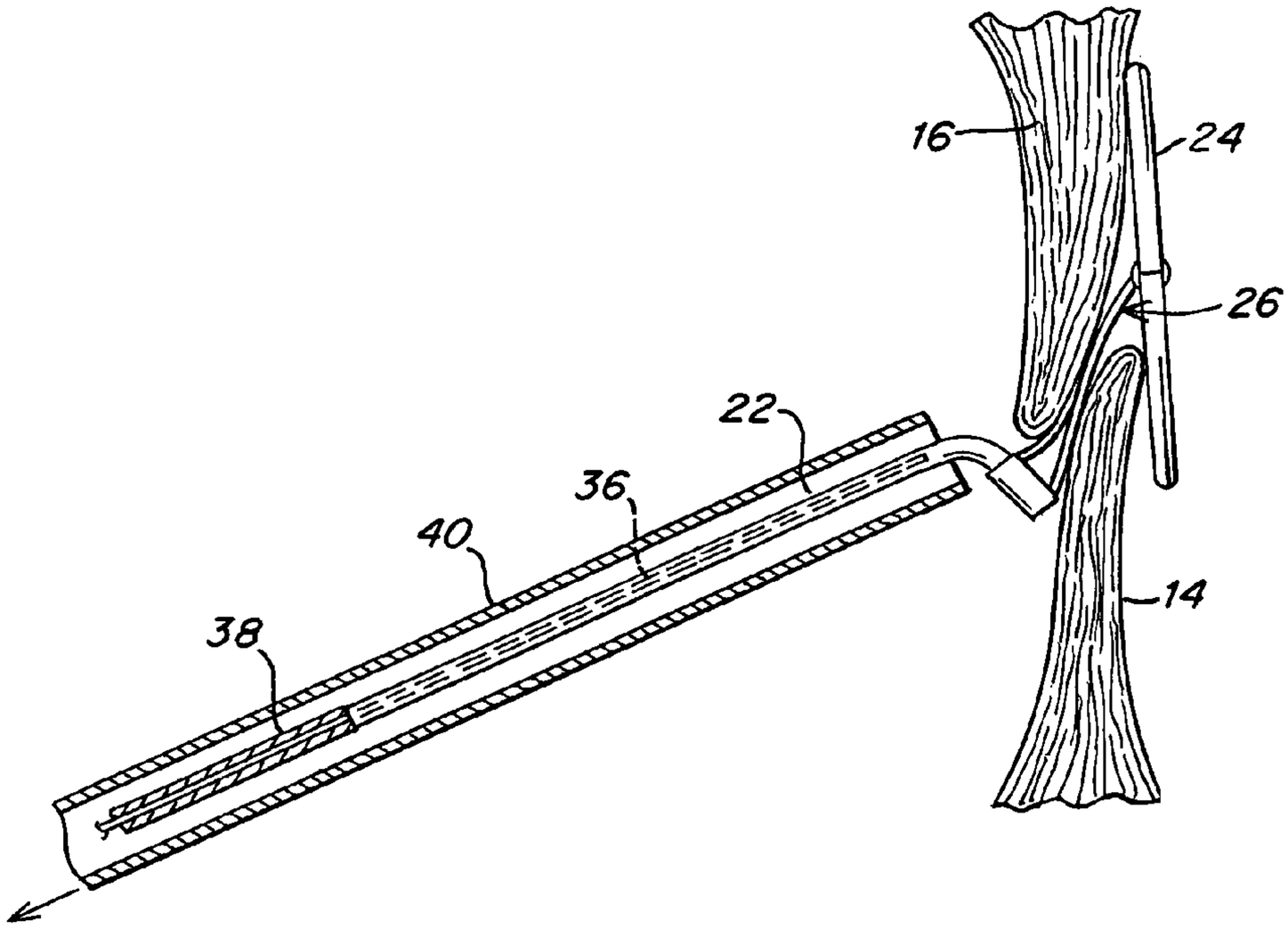

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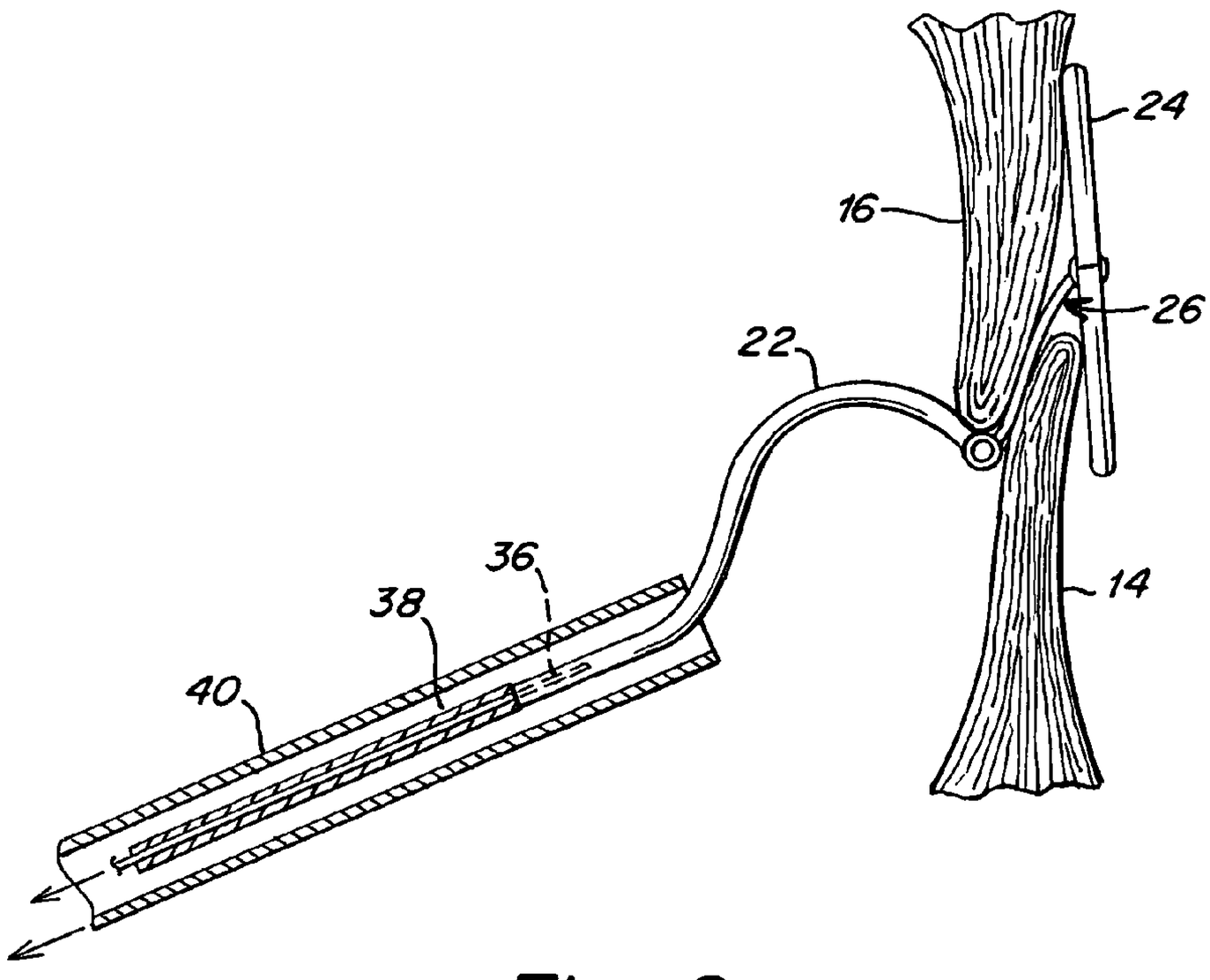

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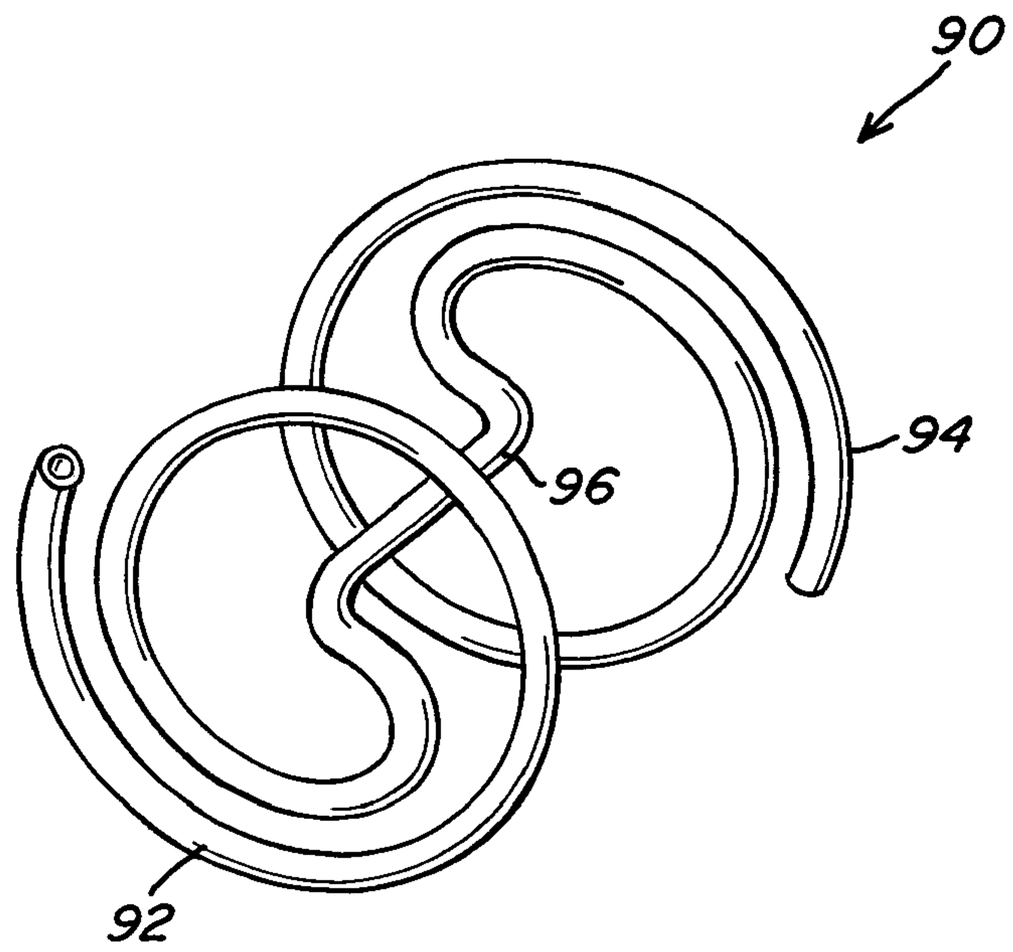

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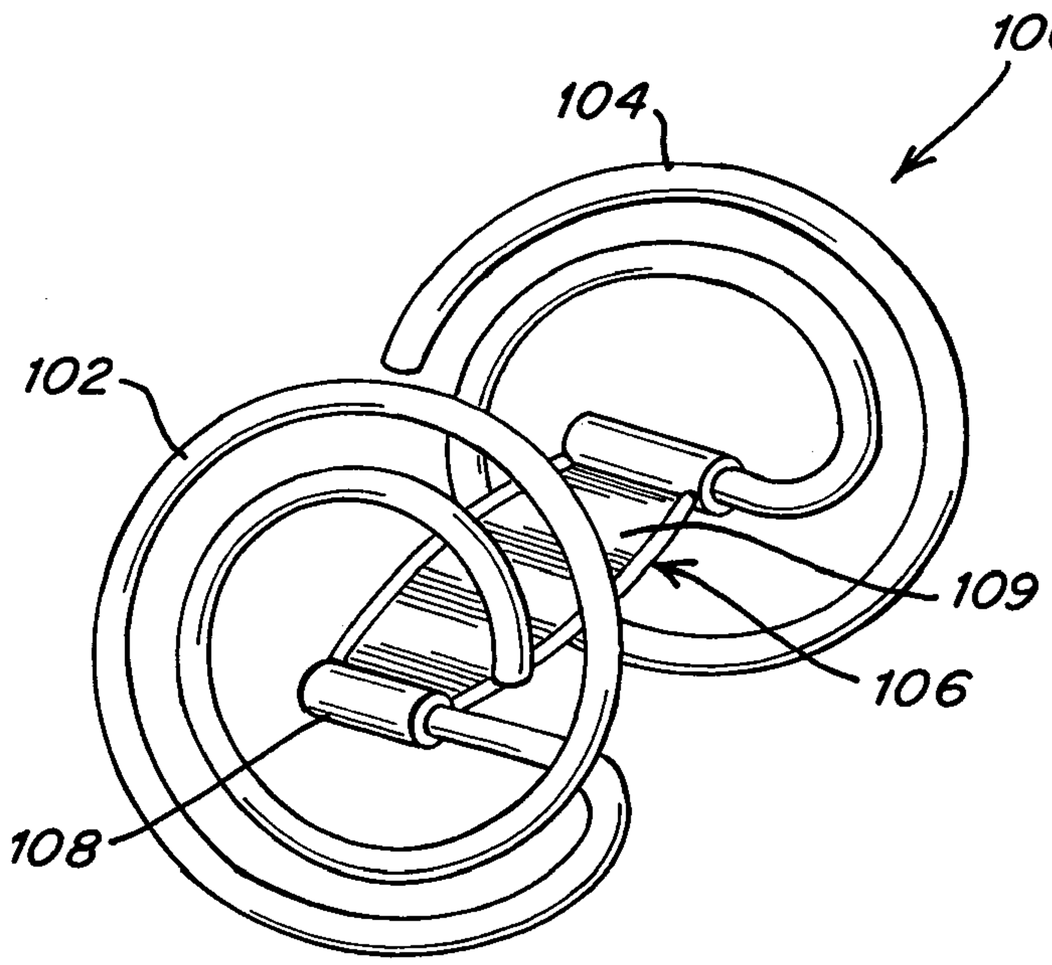

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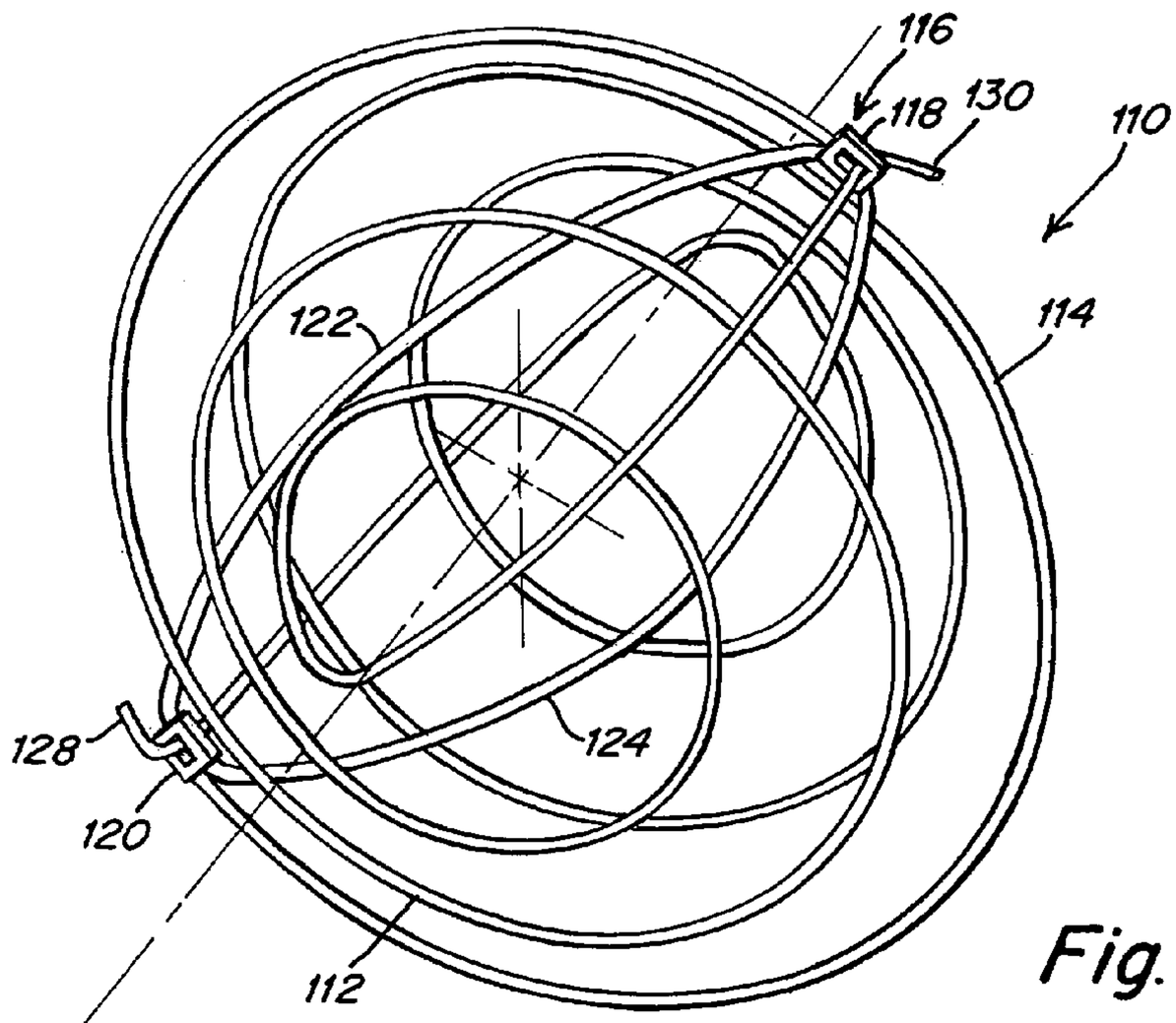
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Fig. 11

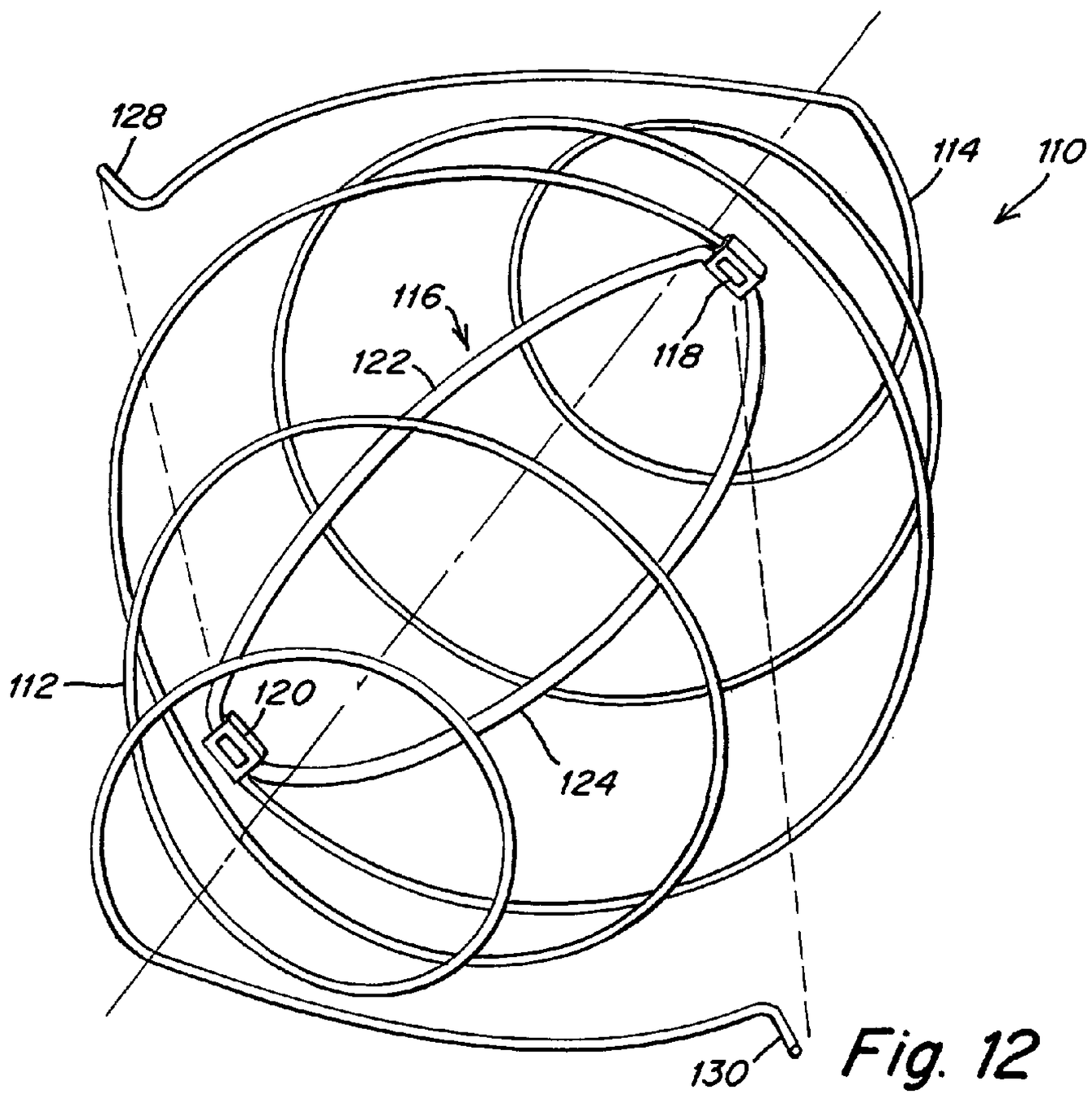
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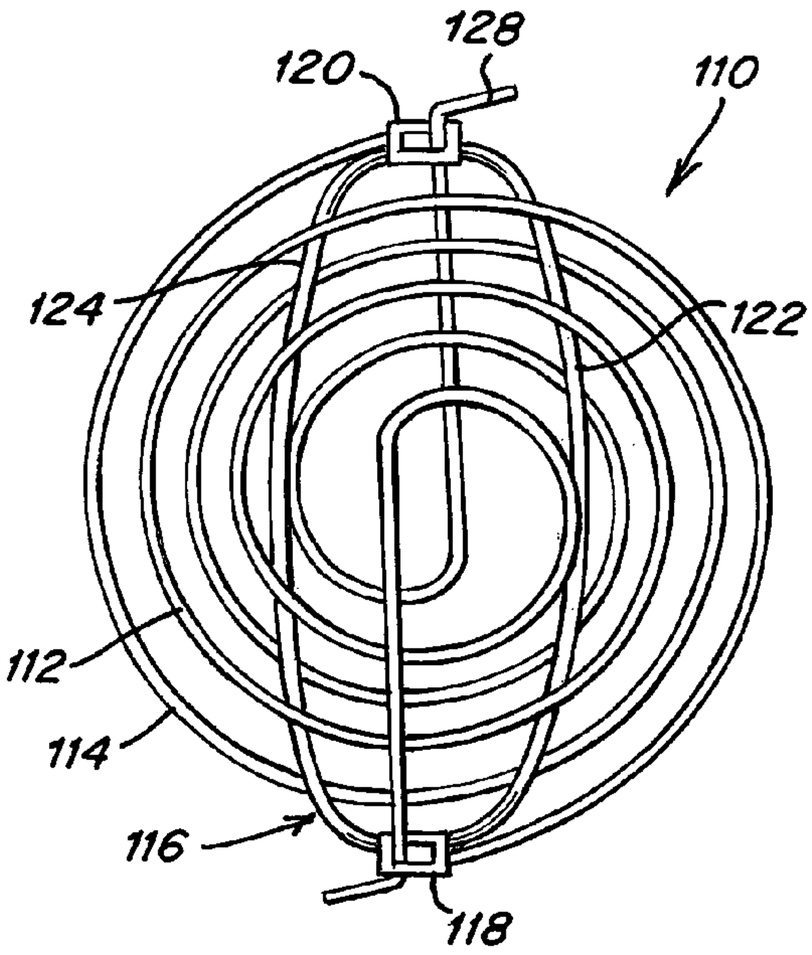
Fig. 12



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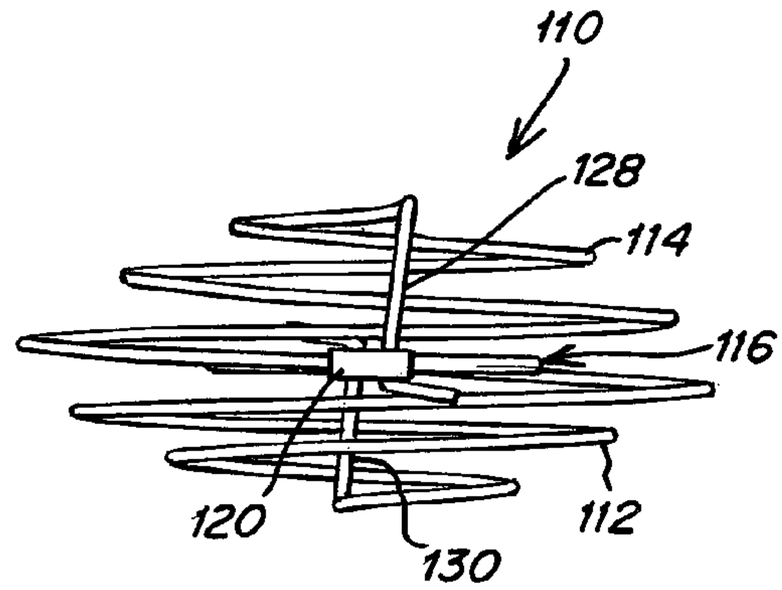
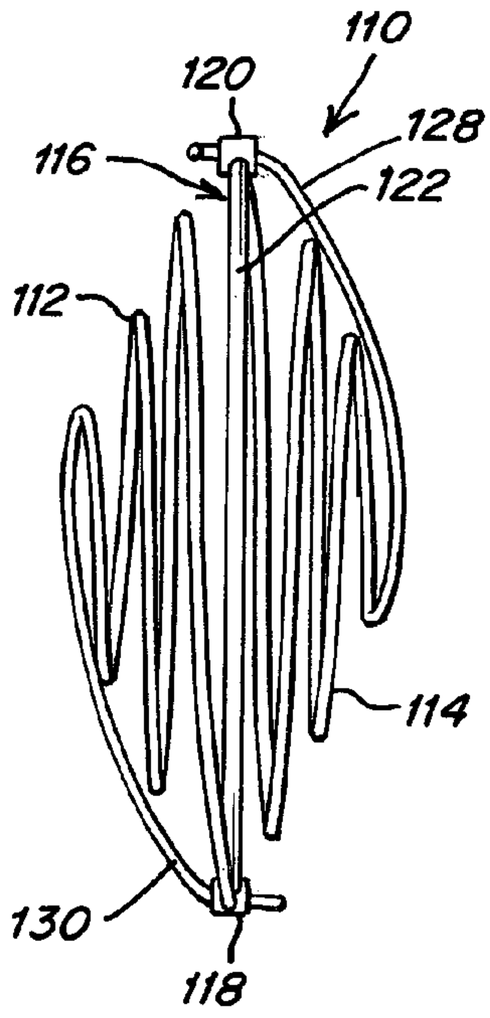


Fig. 14



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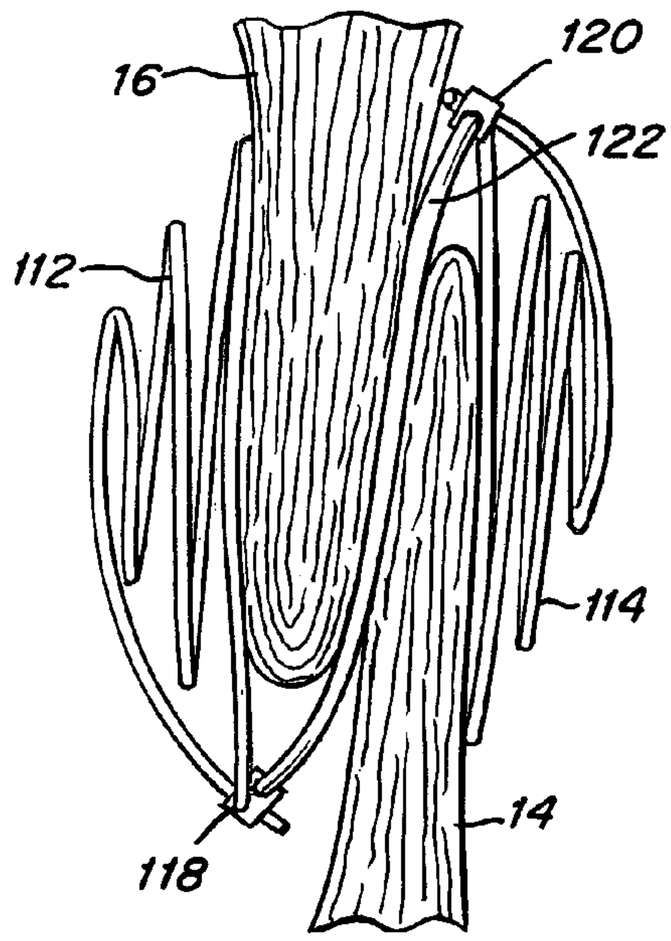

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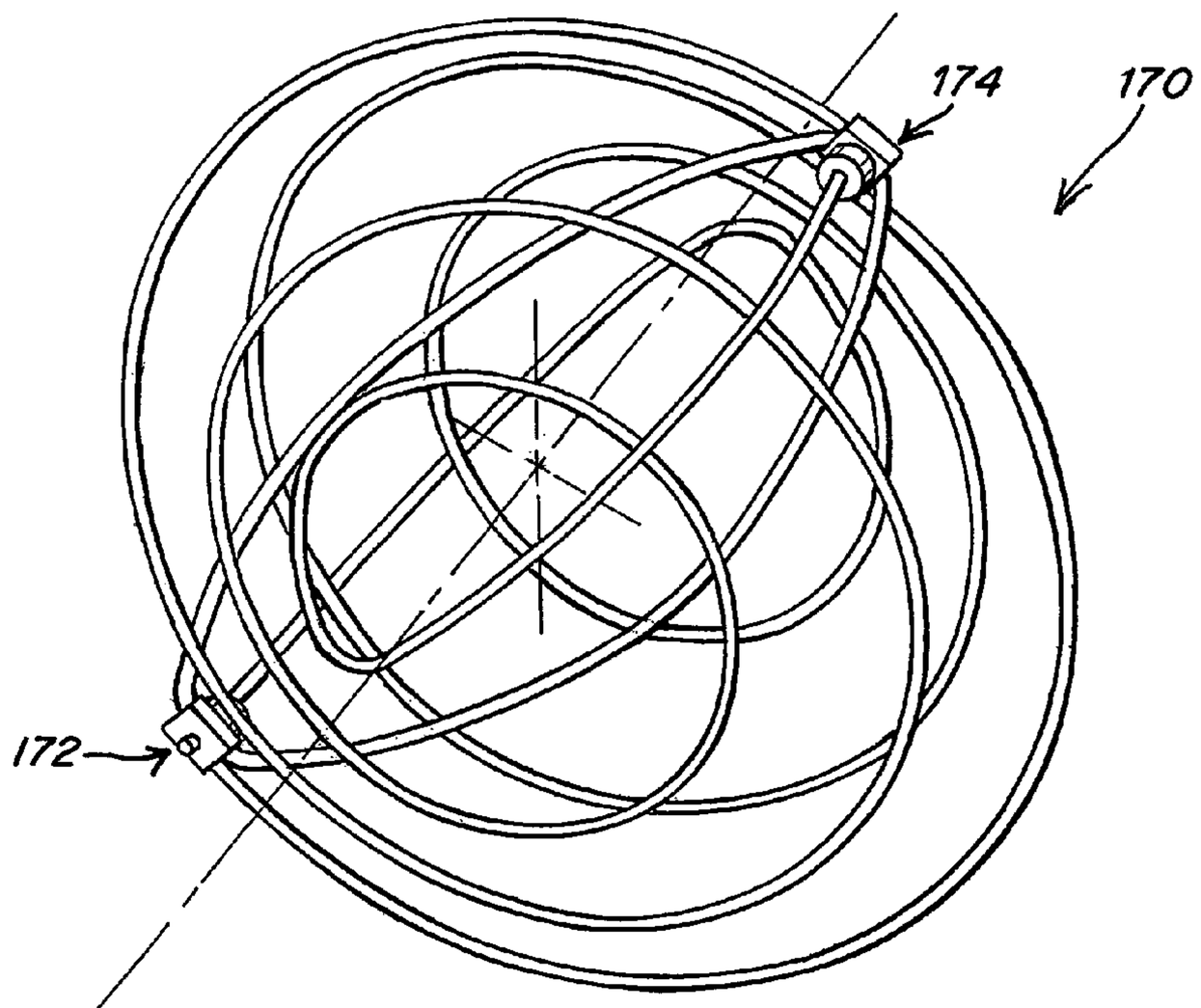

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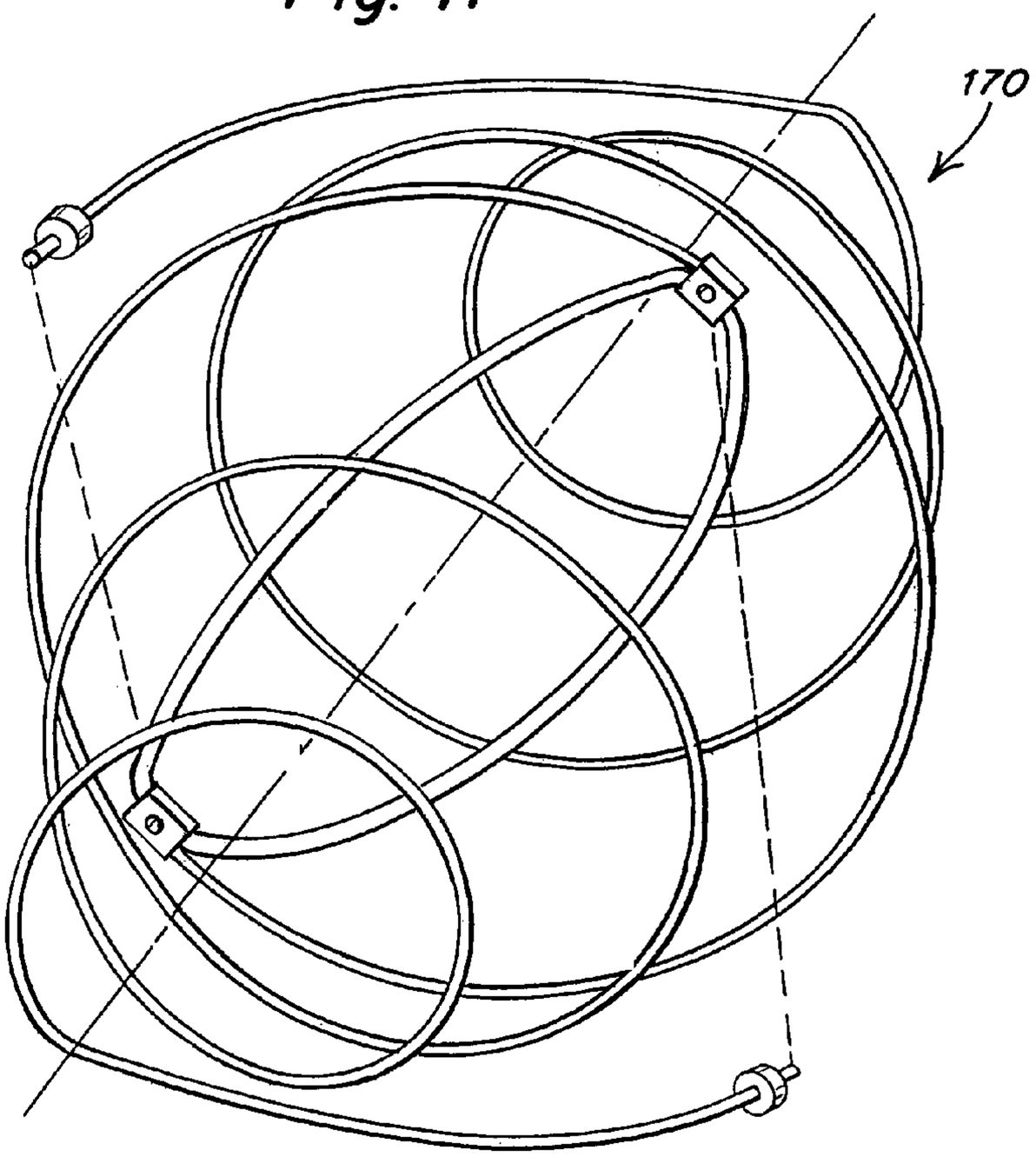


Fig. 18

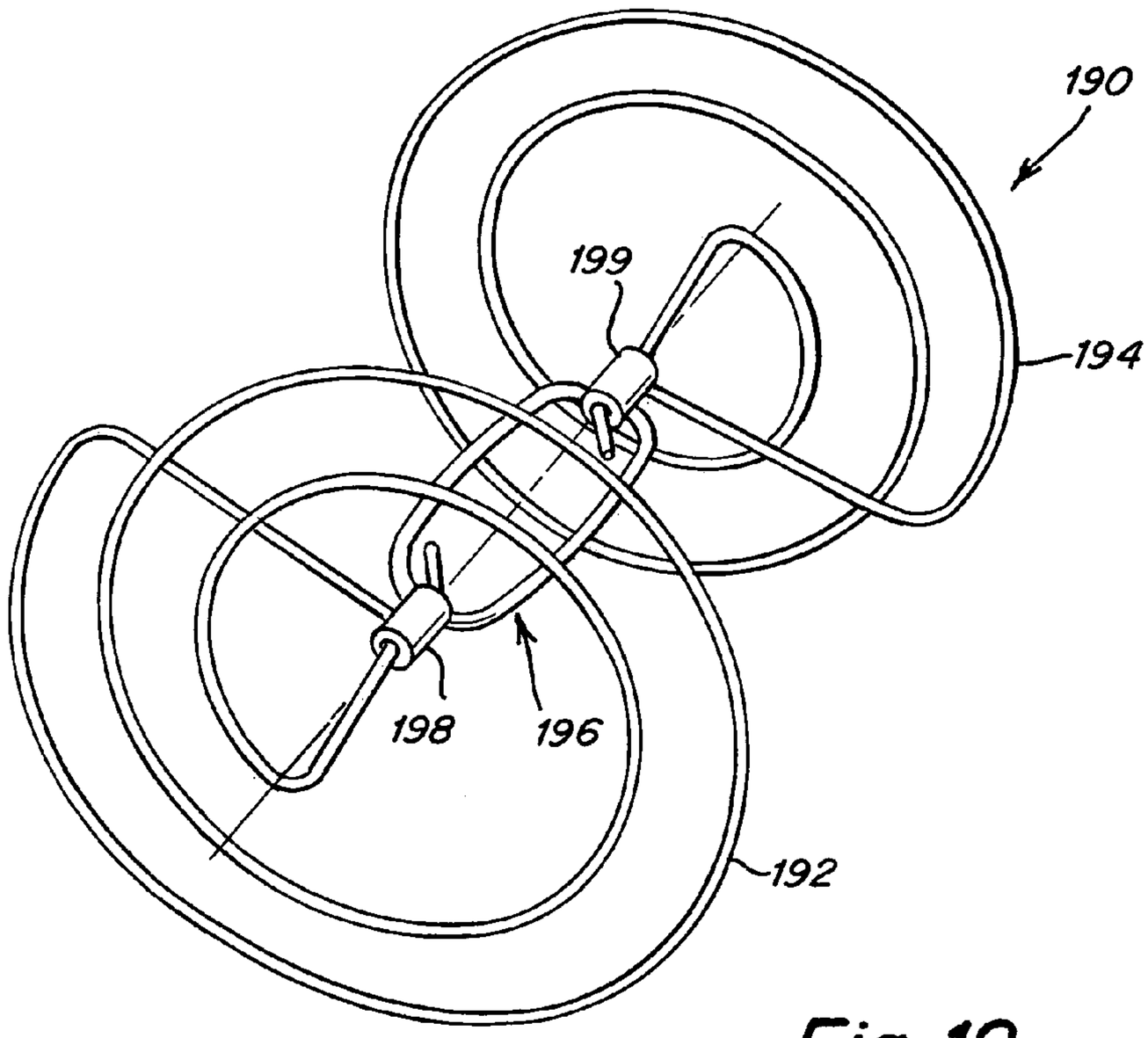


Fig. 19

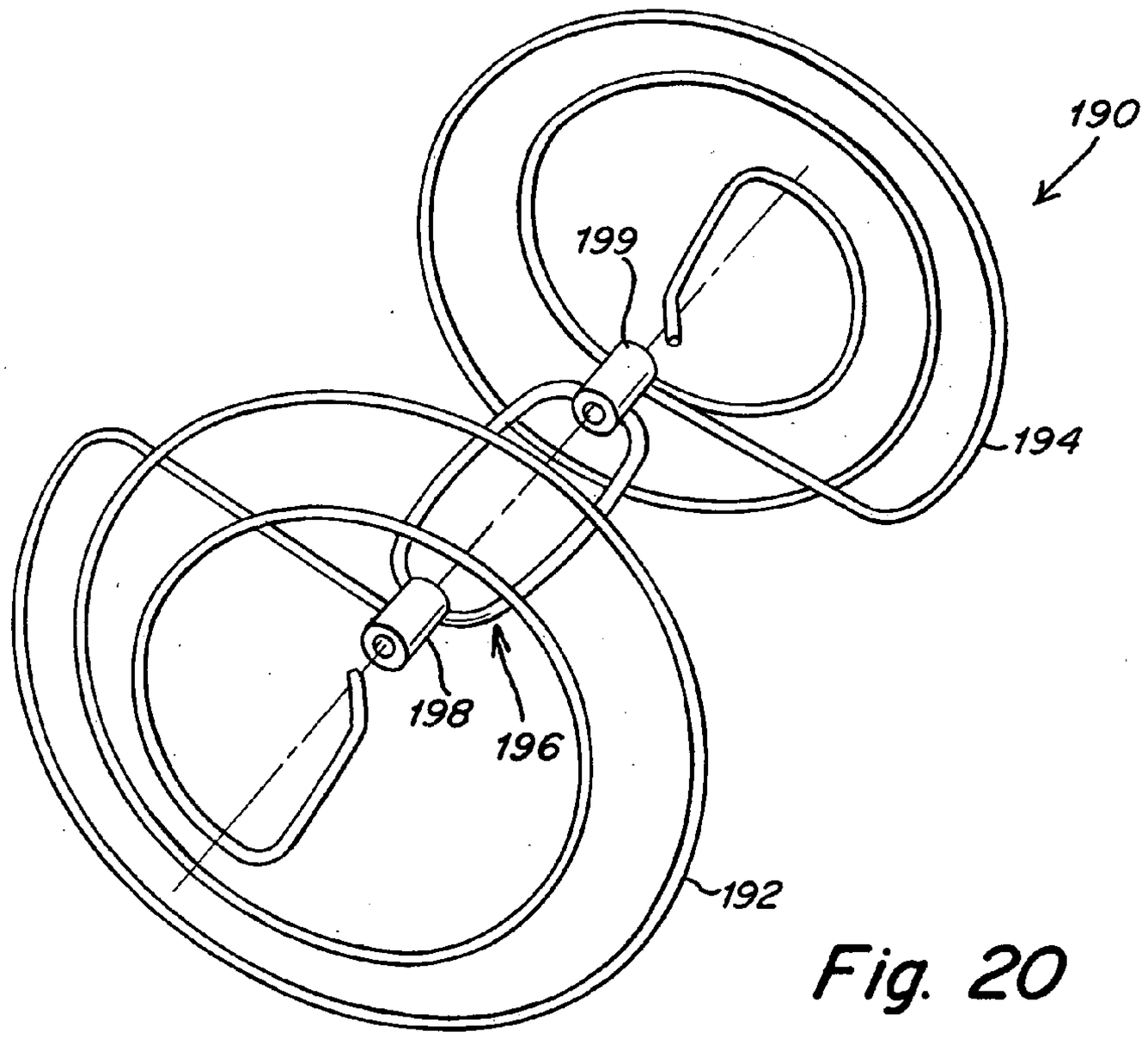
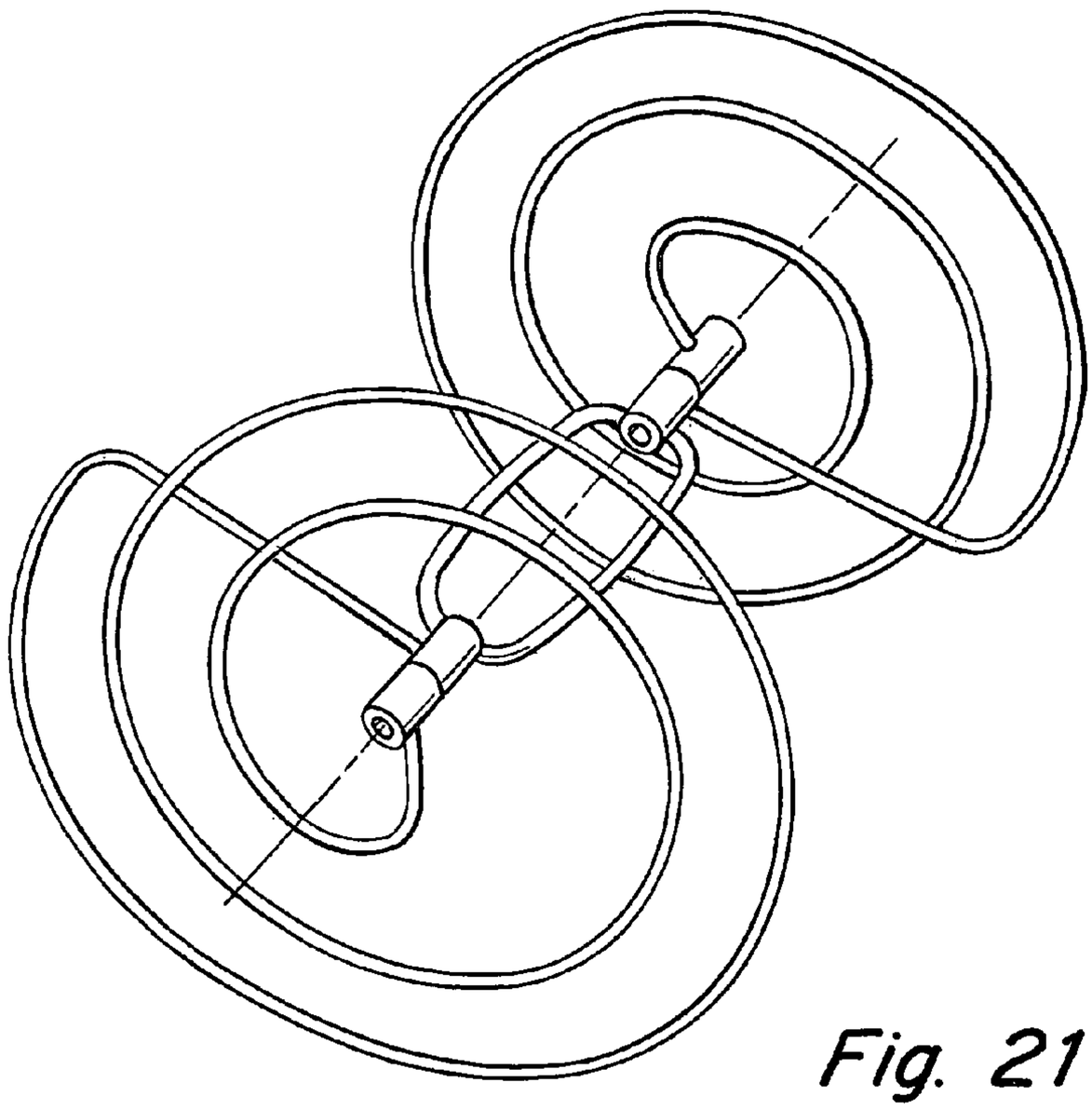


Fig. 20



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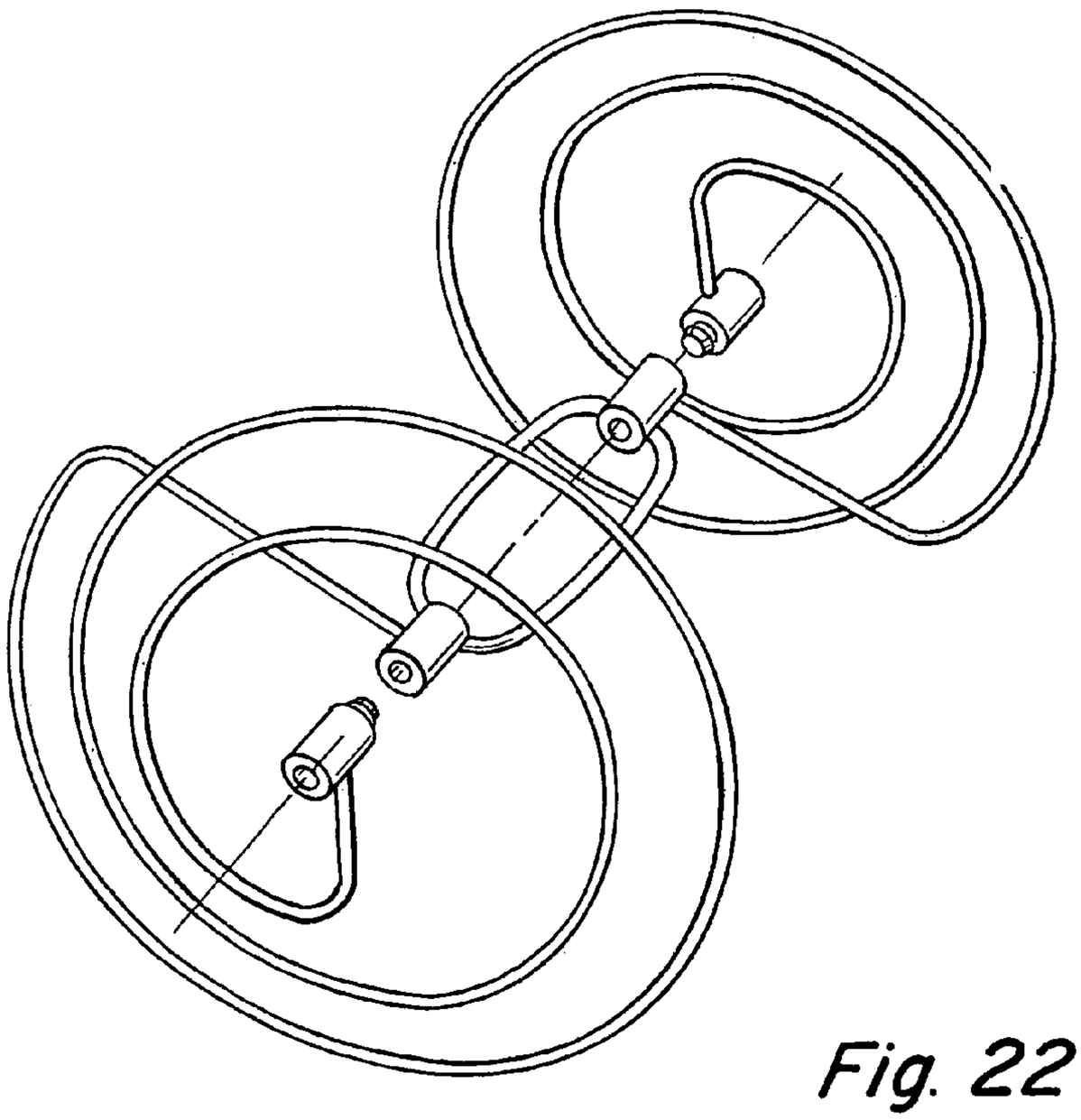

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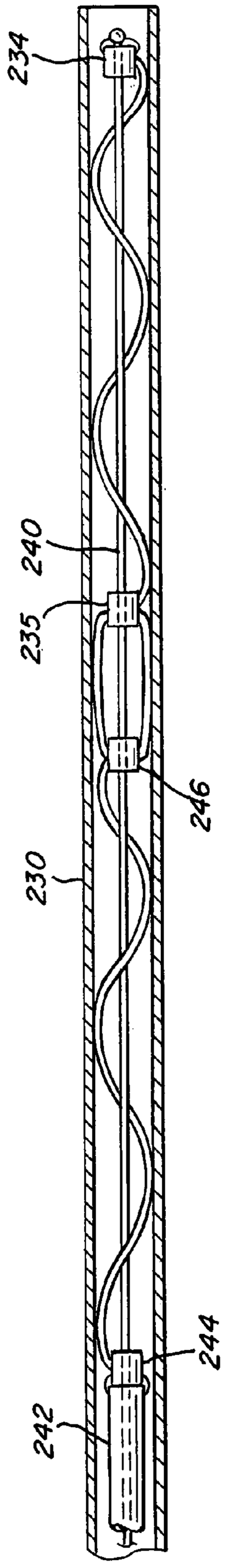

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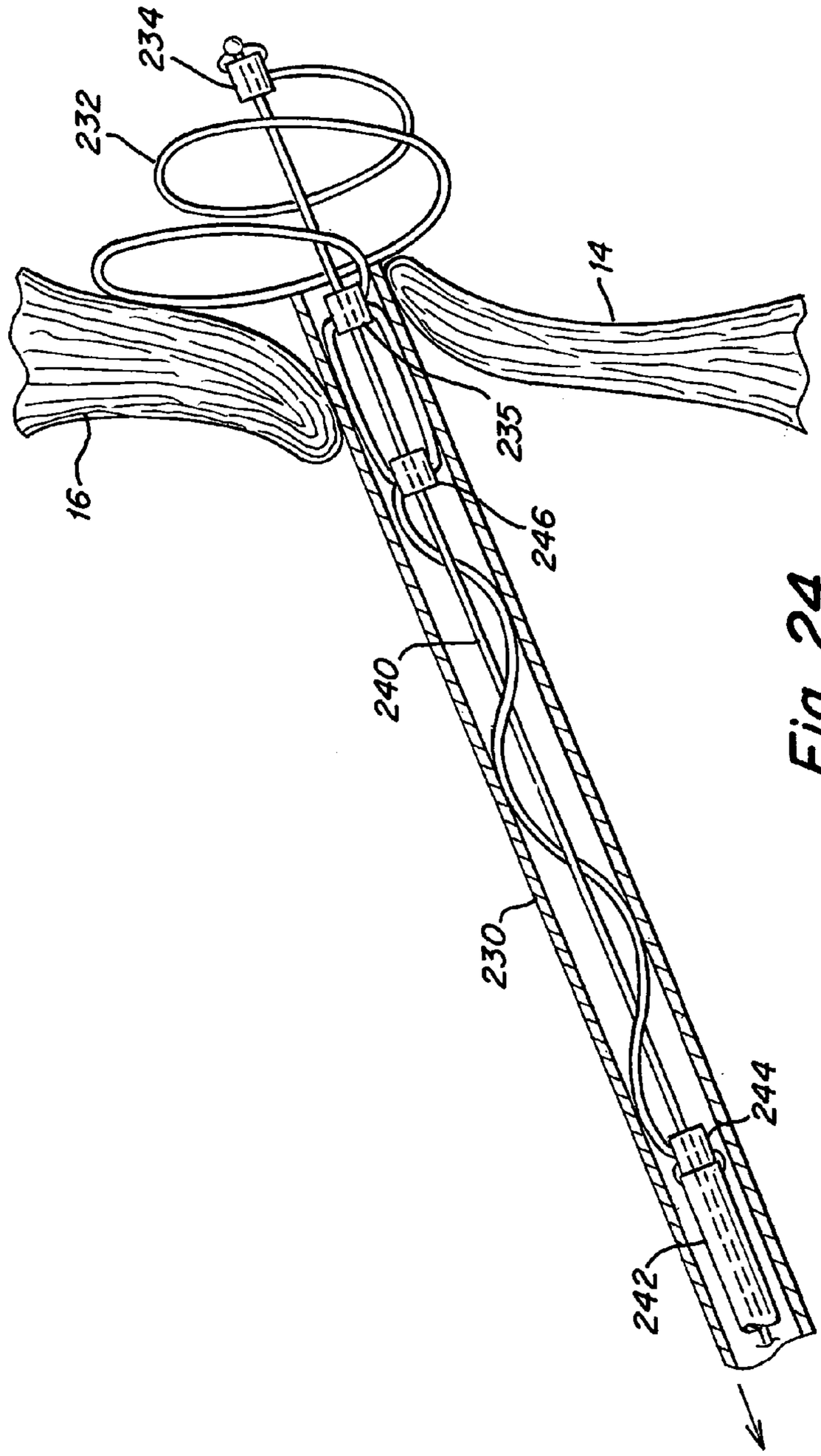

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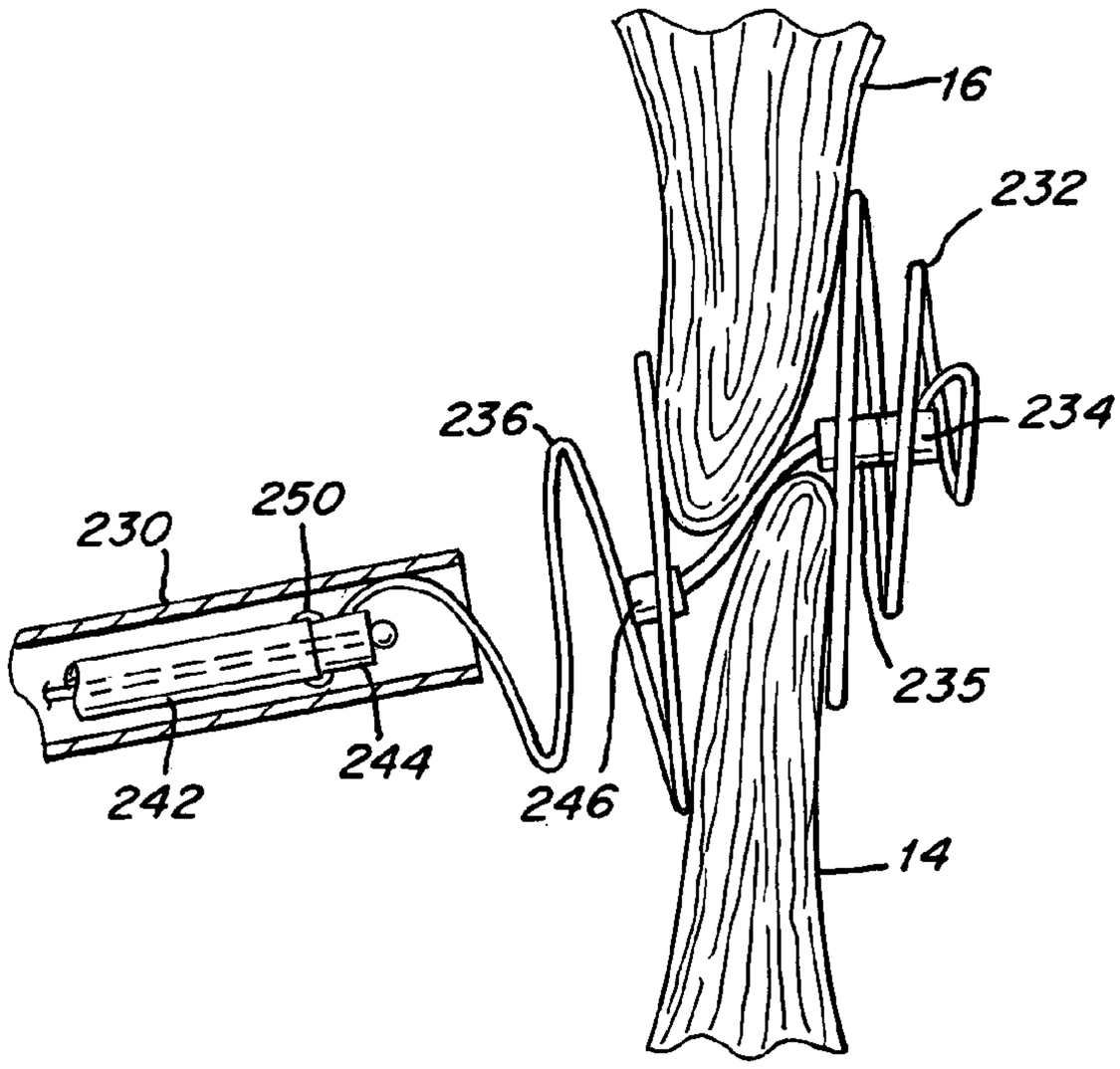
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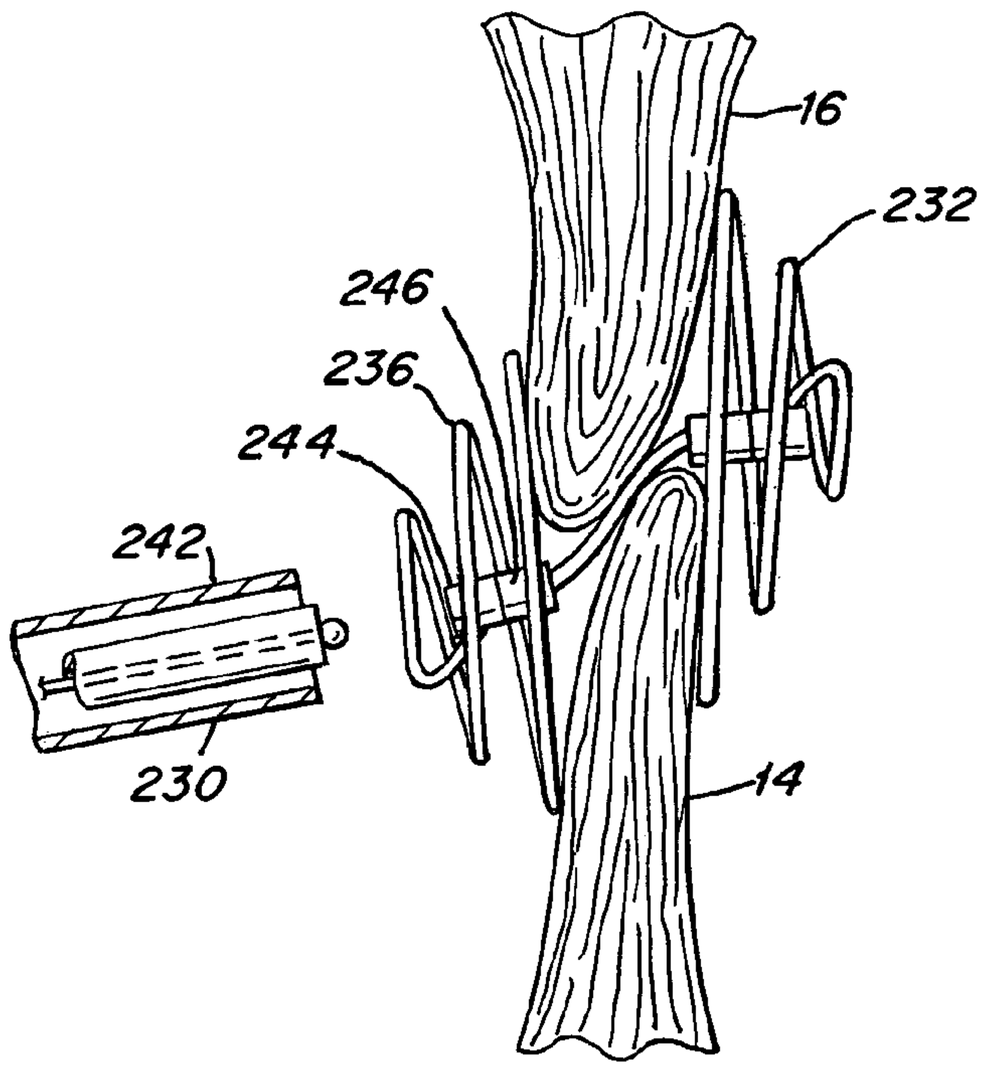
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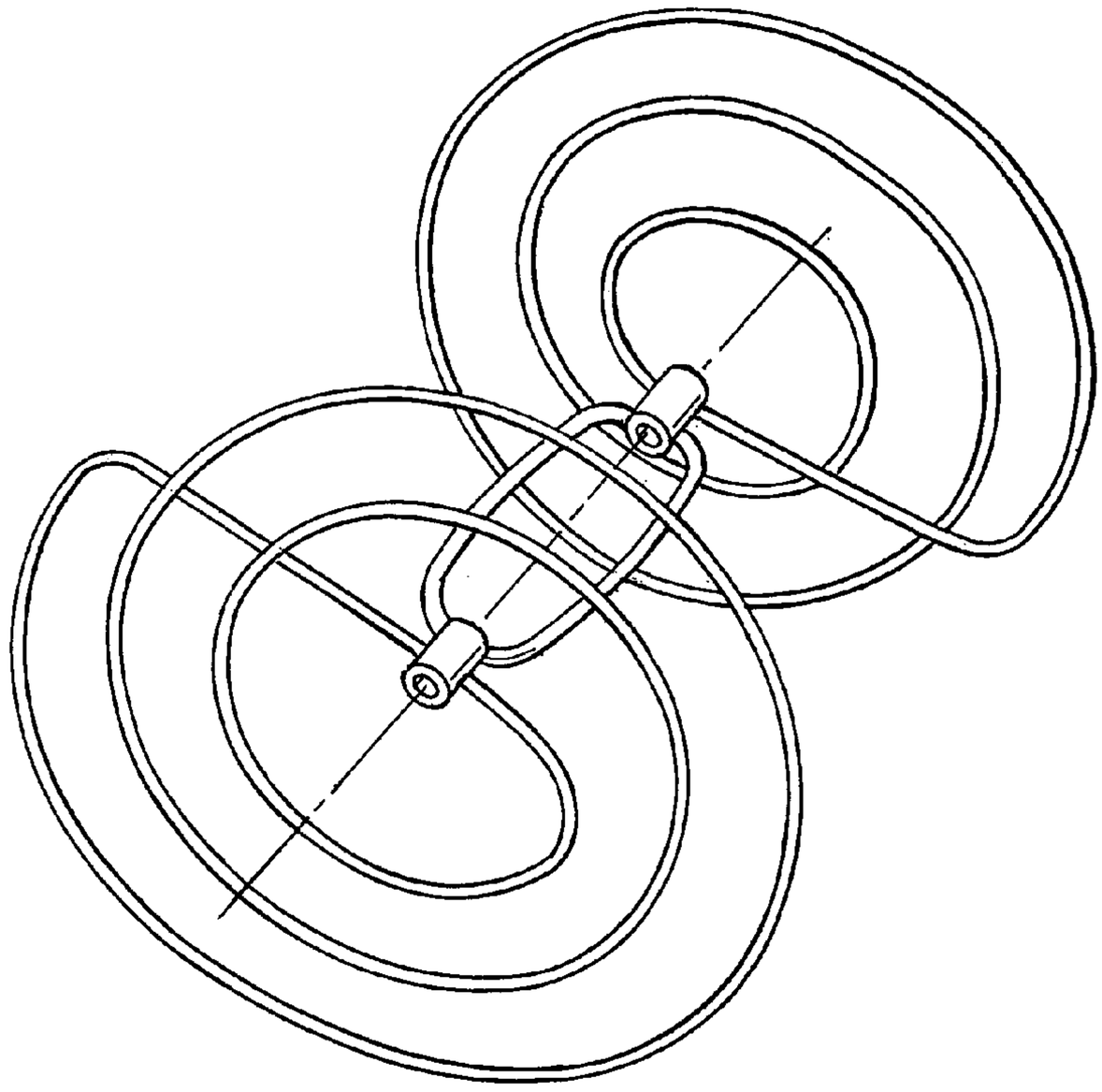
Fig. 26



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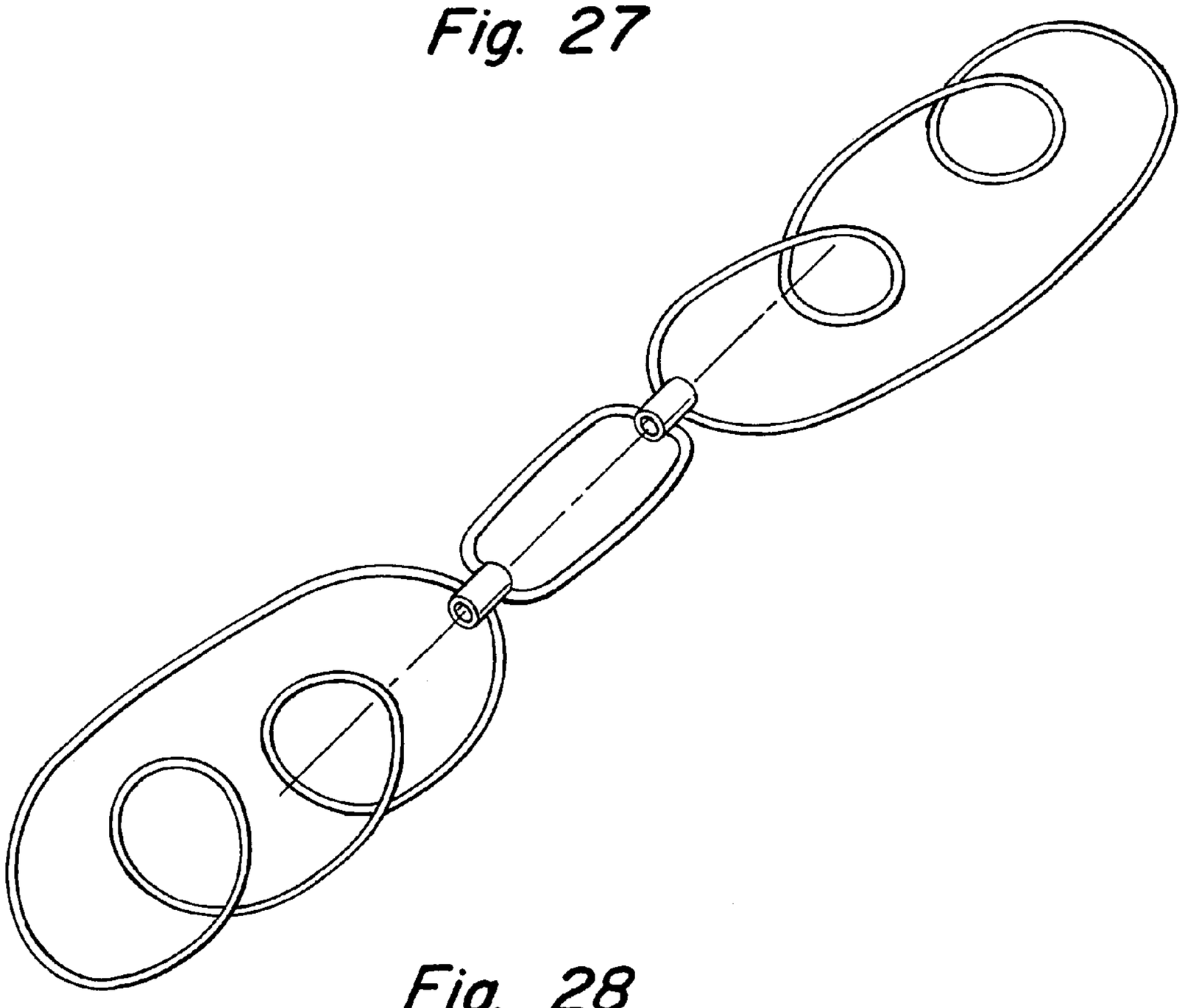

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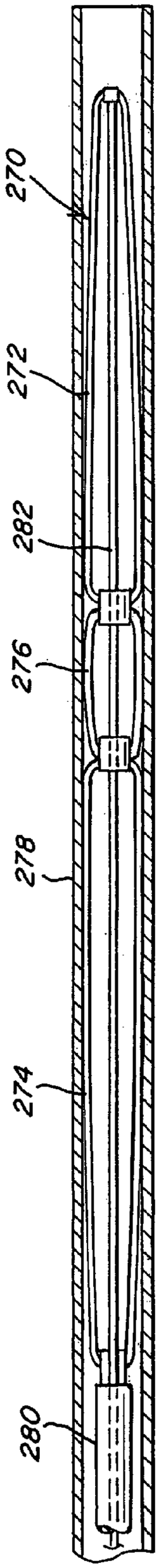

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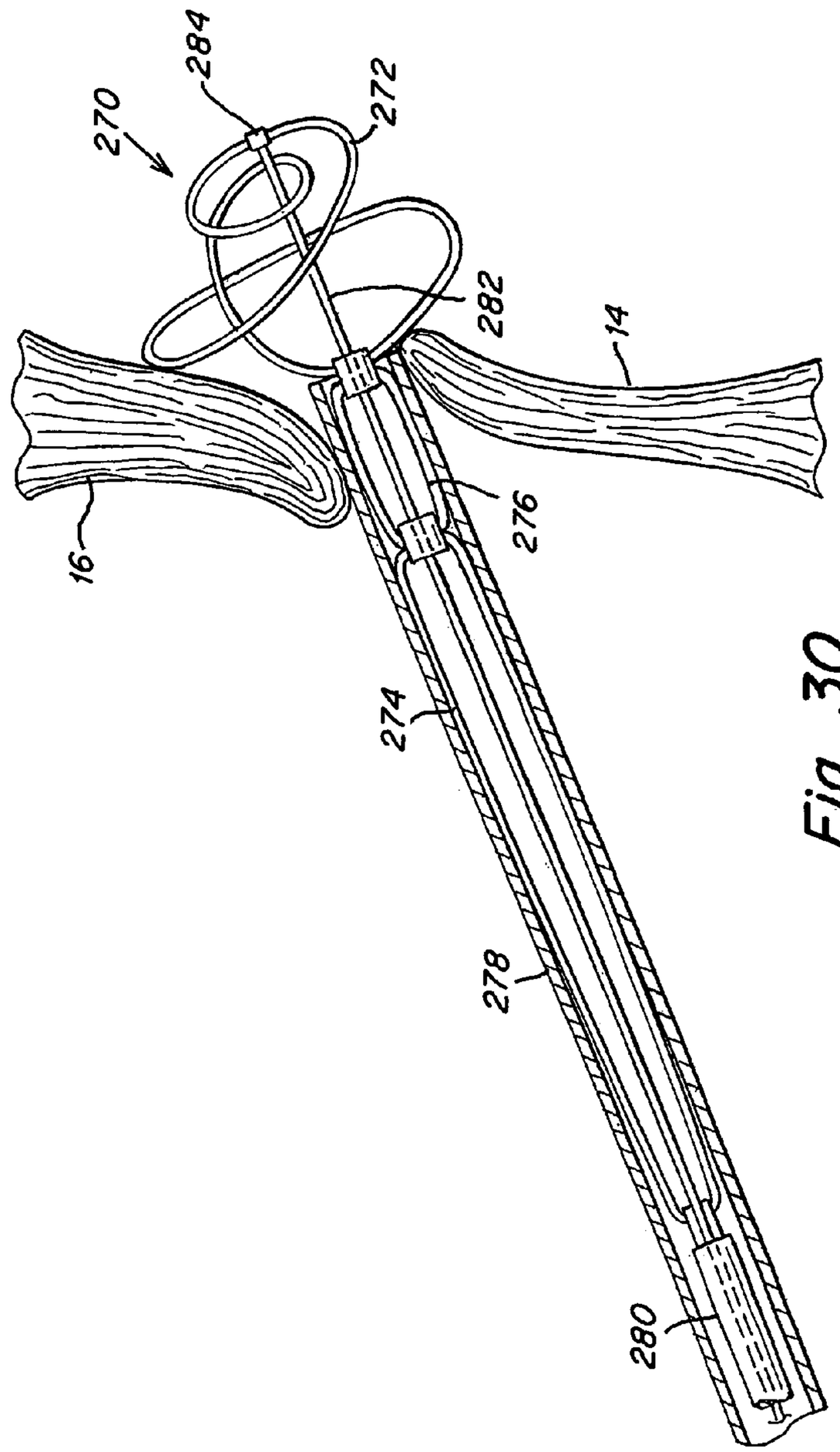

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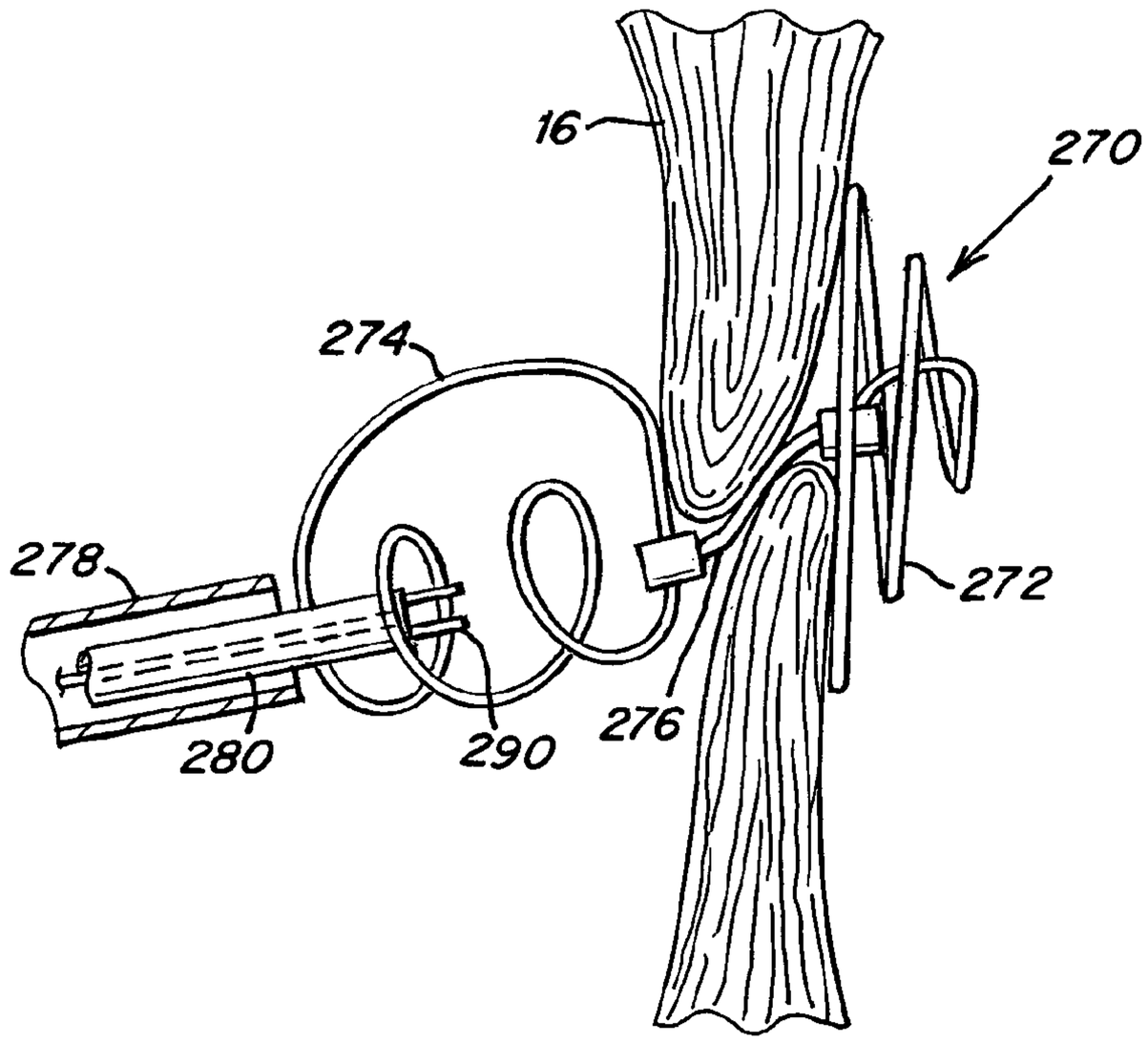

Fig. 31

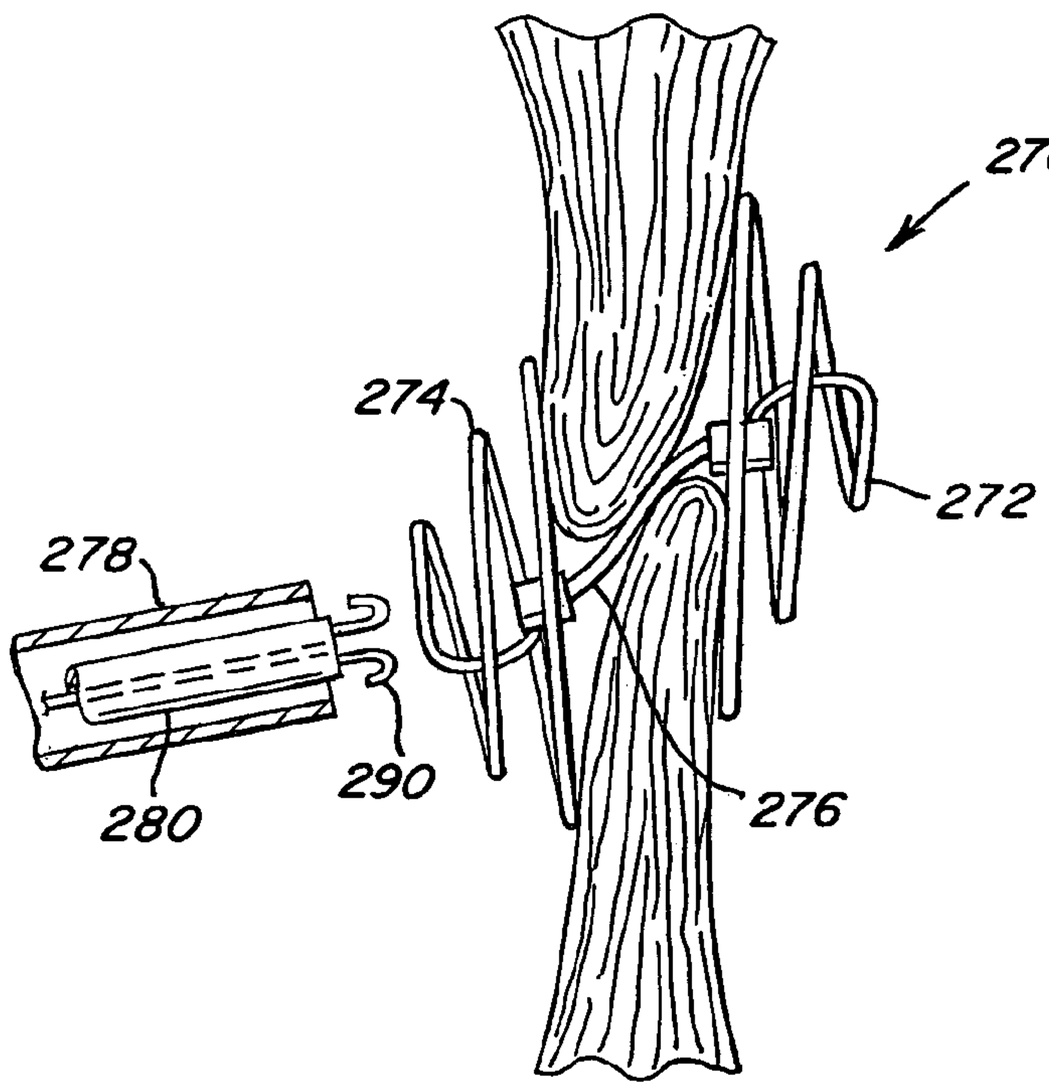

Fig. 32

DOUBLE COIL OCCLUDER

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority from provisional Ser. No. 60/568,526, filed May 6, 2004, which is incorporated herein by reference.

BACKGROUND

This invention relates to an occluder for closing a septal defect.

A PFO, illustrated in FIG. **1**, is a persistent, one-way, usually flap-like opening in the wall between the right atrium **10** and left atrium **12** of the heart. Because left atrial pressure is normally higher than right atrial pressure, the flap formed by septum primum **14** and septum secundum **16** usually stays closed. Under certain conditions, however, right atrial pressure can exceed left atrial pressure, which creates the possibility that blood could pass from the right atrium to the left atrium through a PFO tunnel **18** and allow blood clots to enter the systemic circulation. It is desirable to avoid this situation.

SUMMARY

Embodiments of the present invention relate to an occluder that has a coil on one or both sides of a medical defect, particularly a septal defect such as a patent foramen ovale (PFO). Each coil is preferably provided as a tube that is hollow, with or without a closed end. In some embodiments, the tube can be delivered over a wire.

In the case of use for occluding a PFO, the coils can be designed to provide a compressive force to one or both of septum primum and septum secundum of a PFO. The device can further include a tissue scaffold.

Other features and advantages will become apparent from the following detailed description and drawings.

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross-sectional view showing a patent foramen ovale (PFO).

FIGS. **2**A, **2**B, **3**A, **3**B, and **4** are various side, end, and perspective views of a device according to a first embodiment of the present invention.

FIGS. **5-8** are partial side and partial cross-sectional views showing delivery of the device of the type shown in FIG. **4**.

FIGS. **9** and **10** are perspective views of additional embodiments of a device according to the present invention.

FIGS. **11-16** are perspective, plan, end, and side views of an occluder according to another embodiment of the present invention.

FIGS. **17** and **18** are perspective views of another embodiment of the present invention, which is a variation of the embodiment of FIG. **11**.

FIGS. **19** and **20**, and FIGS. **21** and **22** are perspective views of two additional embodiments of the present invention.

FIGS. **23-26** are partial cross-sectional, partial side views of a device of the type shown in FIG. **22** being delivered to a PFO.

FIG. **27** is a perspective view of another embodiment of the present invention showing coils with outer ends rigidly connected to a center joint.

FIG. **28** is a perspective view showing the device of FIG. **27** in a partially stretched form for loading into a catheter.

FIGS. **29-32** are partial side, partial cross-sectional views showing the delivery of the device of the type shown in FIGS. **27** and **28**.

DETAILED DESCRIPTION

The present invention relates to embodiments of a septal occluder with one or two spiral coils, including a double spiral coil embodiment. The coils are preferably hollow with open or closed ends, and either or both are designed to provide a compressive force when deployed in a septal defect, such as a PFO. While the coils are preferably formed from hollow tubes that can increase the strength of the spirals over solid wires, solid wires could be used. The hollow tubes may also be easier to deliver, and can be provided over a wire. Another double spiral coil design is shown in provisional application Ser. No. 60/528,022, filed Dec. 9, 2003, and in the nonprovisional Ser. No. 11/008,539, filed Dec. 9, 2004, each of which is expressly incorporated by reference.

Referring to FIGS. **2**A-**4**, in this embodiment, an occluder **20** has two coils, a proximal (right atrial) coil **22** and a distal (left atrial) coil **24**. These coils are coupled together through a center joint **26**. This center joint has a first collar **28** at an inner end of coil **22**, a second collar **30** at an inner end of coil **24**, and connecting rods **32** and **34** coupling collars **28** and **30**. As indicated in FIGS. **2**B and **3**A, rods **32** and **34** are preferably in a horizontal plane in a position shown in FIG. **4** in a manufactured and non-deployed position.

Referring to FIG. **3**B, when occluder **20** is in the deployed position in a PFO, coils **22** and **24** each have an upper portion in contact with septum secundum **16** and a lower portion in contact with septum primum **14**. As is also indicated, rods **32** and **34** and center joint **26** can extend side-by-side in, and conform to, the geometry of the PFO tunnel between septum primum **14** and septum secundum **16**.

The coils can be made from a number of different materials, including metal or nonmetal. Among nonmetals, a preferable material is a polymer, which can be a bioresorbable polymer. In this embodiment, the ends of the coils are shown as being open, but one or both of the ends could be closed, either with a solid piece or with a mesh. In this embodiment, the coils spiral outwardly from a central location.

As shown in FIG. **5**, the device with coils in the form of hollow tubes can be mounted over a wire **36** that extends through an inner catheter **38**. Wire **36** and catheter **38** are both in a delivery sheath **40**. The device with coil **24**, coil **22**, and center joint **26** is in a substantially elongated and a low profile configuration, such that they fit into a sheath that is preferably **10** French or smaller, although a larger sheath could be used.

As shown in FIG. **5**, sheath **40** is inserted into the left atrium. Referring to FIG. **6**, sheath **40** and wire **36** are retracted, while inner catheter **38** is maintained in its current position to hold the position of coil **24**. These relative movements, which can be at the same or at different rates, allow coil **24** to be released from delivery sheath **40** and into the left atrium. The coil is preferably formed from a material with good shape memory properties so that it returns to its coil form when released from sheath **40**. Such a material is especially useful when the coil has a free outer end not connected to anything else.

Referring to FIGS. **7** and **8**, sheath **40** and wire **36** are retracted further while inner catheter **38** is used to help maintain conduit **22** in a desired position. With such further removal, the center joint is positioned within the PFO tunnel, and coil **22** is allowed to resume its coil shape on the right atrial side of the PFO.

The device is formed with suitable materials, dimensions, and configuration so that the coils provide enough compressive force to hold together septum primum and septum secundum sufficiently to prevent clots from passing from the right atrial side to the left atrial side. As will be apparent below, while occluder **20** has a spiral that is connected to a center joint and spirals outwardly (i.e., with an increasing radius) to a free end, in other embodiments, the coil spirals inwardly from the center joint and may have an end that is connected to the center joint. In this embodiment and others, the outer surface can be roughened to produce an inflammatory effect to encourage healing. In this embodiment and others, a single coil can be used on one side of the defect, with another structure, such as an umbrella-shaped structure on the other side of the defect.

FIG. **9** is a perspective view of another embodiment of the present invention in which a device **90** is formed from a single, monolithic hollow tube shaped to form a distal coil **94**, a proximal coil **92**, and a connecting segment **96** that extends from the inner ends of coils **92** and **94**. If desired, portions of device **90**, such as at connecting segment **96**, can have whiskers that can be formed by gluing short threads of the material used to make the tube or some other material, or connecting segment **96** can be partially shaved or otherwise frayed. The use of whiskers can serve as an inflammatory agent that encourages healing. While mentioned here, whiskers could be used in other embodiments.

Like the embodiment of FIG. **2***a*, the inner ends (i.e., smaller radius portion) of the coils are coupled to a connector or transition to a connecting segment, and the outer ends of the coils are free and are not connected to any other structure.

Referring to FIG. **10**, in another embodiment of the present invention, a device **100** has a proximal coil **102** and distal coil **104**. In this case, one of the coils, in this case coil **102**, starts spiraling from the inside where there is a free end, and spirals out with increasing radius to an outer end of coil **102** where the coil is then curved away from the plane of the spiral and is connected to a collar **108** of a center joint **106**. Distal coil **104** is shaped in a similar manner.

As is further indicated in FIG. **10**, a tissue scaffold **109** can be incorporated into center joint **106**. The scaffold is connected between the collars and can be bounded by the connecting rods between the collars, although it could be used at other locations instead of this location or additionally at other locations. While shown between the connecting rods, it can extend around the connecting rods and/or around other portions of the device to encapsulate them. The tissue scaffold promotes encapsulation and endothelialization, thereby further encouraging anatomical closure of septum primum and septum secundum. While shown just in FIG. **10**, a tissue scaffold can be incorporated into other embodiments.

A tissue scaffold can be formed of any flexible, biocompatible material capable of promoting tissue growth, including but not limited to polyester fabrics, Teflon-based materials, such as ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM) or other bioengineered materials, synthetic bioresorbable polymeric scaffolds, other natural materials (e.g. collagen), or combinations of these materials. A tissue scaffold or the spiral or center joint can have drugs or biological agents to improve the defect healing process and/or to prevent clotting.

Referring to FIGS. **11-16**, a device **110** according to still another embodiment can have close-ended hollow or solid spirals, and can have a free end of a coil on one or both sides of a defect locked to a center joint (FIG. **11**) or unlocked (FIG. **12**). By locking one or both free ends of a spiral to a center joint, the clamping force of the device can be increased relative to a device with a free end.

A center joint **116** has a latching loop **120** connected to an outer end of coil **114**. From the inner end of coil **114**, there is a free end **128** that can extend a short distance through loop **120**. Similarly, coil **112** has an outer end attached to a latching loop **118** and an inner end that extends to a free end **130** that extends a short distance through the opening in loop **118**. Free ends **128** and **130** each have a bent end that extends through latching loops **118** and **120** in a manner that they stay in the latched position. Latching loops **118** and **120** are connected together with connecting rods **122** and **124**.

Additional views of this device are shown in FIGS. **13-15** and in FIG. **16** which shows the device as deployed. FIG. **15**, in particular, shows how the latching loops **118** and **120** are coupled to the outer ends of the spiral, the spirals extend inwardly, and at the inner end of the spiral, a free end **128**, **130** extends to the latching loop on each side. As is also shown in FIG. **16**, the connecting rods **122** and **124** (not shown) have some ability to bend and conform to the geometry of the PFO tunnel, while the spirals can provide a compressive force between septum primum and septum secundum.

FIGS. **17** and **18** show an embodiment of a device **170** that is similar to that in FIGS. **11** and **12**, except that rather than having free ends extending a short way through loops and held in the loops with bent ends, it has locks, such as magnetic locks, **172**, **174** on the free ends. In this case, the free end has one magnetic piece and the center joint has another magnet and a conforming mechanical structure, such as a short lug and an opening for receiving the lug.

Referring to FIGS. **19** and **20**, a device **190** has features of several of the embodiments above. The device has a proximal coil **192** and a distal coil **194** connected together through a center joint **196** that includes collars **198** and **199**. Coil **192** is rigidly connected to a side of collar **198** from where it extends radially outwardly and then spirals inwardly until at an inner part of the spiral, it bends toward the center. At the center, there is a bent end that can extend through collar **198** to hold it in place. In this case, the interior end of the loop has a bent end for engaging the collar, but it could have the reverse form with the inner end of the spiral connected to the collar and the outer end of the spiral curved to extend through the collar. Coil **194** in this embodiment is similarly connected to the other side of the device, although the different coils can have different structures.

FIG. **20** shows device **190** of FIG. **19** with the inner ends of the coils detached from the respective collars.

FIGS. **21** and **22** show embodiments similar to those in FIGS. **19** and **20**, except that the connection between the spiral and the center joint has a snap fit to hold them together. The device is shown with the center joint and spiral detached in FIG. **22**. In this case, like the embodiment of FIGS. **19** and **20**, the coil spirals inwardly from the outside to a lock, but it could have the reverse form of spiral.

FIGS. **23-26** show the delivery of a device of the type shown in FIGS. **21** and **22**. FIG. **23** shows the device of FIG. **21** loaded into a sheath **230**, and coupled to a mandrel **240** and a delivery catheter **242**. As shown herein, the device has a small profile, preferably small enough to fit in a 10 F sheath. Referring to FIG. **24**, sheath **230** with the loaded device is provided through the PFO tunnel and into the left atrial side. Sheath **230** is then retracted while an end cap **234** of distal coil **232** is held in place by mandrel **240** to allow a distal coil **232** and end cap **234** to be released from sheath **230**. A proximal end cap is held in place with delivery catheter **242**.

Referring to FIGS. **25** and **26**, end cap **234** coupled to collar **235**, e.g., with a snap fit, and mandrel **240** (not shown here) is

withdrawn. Sheath **230** is then further retracted to release a proximal coil **236** against septum primum **14** and septum secundum **16** on the right atrial side until end cap **244** is coupled to collar **246**. Delivery catheter **242** is releasably detached from end cap **244**, resulting in the positioned device as shown in FIG. **26**. The releasable connection between catheter **242** and end cap **244** can be with grappling hooks **250** (FIG. **25**), which are generally known for use in delivering medical devices.

FIGS. **27** and **28** show another embodiment of the present invention similar to that shown in FIGS. **21** and **22**, except that the device is shown with a center joint that has a rigid and generally non-separable connection to both coils. FIG. **28** shows the device of FIG. **27** in an elongated form as it would be loaded into a sheath for delivery. With further elongation, the profile of the device can be reduced to fit inside a delivery sheath as shown in FIG. **29**.

FIGS. **30-32** show the release of the device of FIGS. **27** and **28** in the PFO tunnel. This delivery is generally similar to that described in conjunction with FIGS. **23-26**. A device **270** with a distal coil **272**, proximal coil **274**, and center joint **276** is elongated as shown in FIG. **28** and loaded into a delivery sheath **278**. A first delivery catheter **280** is releasably connected to a portion of coil **274** at a proximal end, and a second delivery catheter **282** is releasably connected to a portion of distal coil **272** with a connection **284**. As shown in FIG. **30**, sheath **278** is withdrawn while second delivery catheter **282** holds distal coil **272** in place so it can open into a coil on the left atrial side. As shown in FIGS. **31** and **32**, sheath **278** is further retracted to allow right atrial coil **274** to open on the right atrial side. Coil **274** as shown is releasably held with hooks **290** to provide control over the release. Having described embodiments of the present invention, it should be understood that modifications can be made without departing from the scope of the invention.

What is claimed:

1. A device adapted to press together the septum primum and the septum secundum between the atrial chambers, the device comprising:

first and second clamping spirals, each having a size suitable for use on each side of the septum, wherein each of the first and second clamping spirals has a first end at an outer edge and a free end; and

a central connector for connecting the first end of the first and second clamping spirals and passing through the tunnel between the septum primum and the septum secundum,

wherein at least one of the spirals includes a length of wire extending in a radial direction from an inner portion of the spiral to the outer edge of the spiral and locking the free end of the spiral to the central connector.

2. The device of claim **1**, wherein the spirals spiral outwardly from the central connector to the free ends.

3. The device of claim **1**, wherein the central connector includes at least one hollow rod extending from a central region of the first spiral to a central region of the second spiral.

4. The device of claim **1**, wherein the spirals and the central connector are formed from a single wire.

5. The device of claim **1**, wherein at least one of the spirals has a radially extending portion extending from the central connector, the at least one spiral extends inwardly back to the central connector, and the center joint is flexible.

6. The device of claim **1**, wherein the device is formed from a bioresorbable polymer.

7. The device of claim **1**, wherein the spirals each circle around more than 360°.

8. The device of claim **1**, wherein the central connector includes a scaffold for promoting tissue growth.

9. The device of claim **1**, wherein the first end of each of the first and second spirals includes a radial portion connected to the central connector.

10. The device of claim **1**, wherein the central connector has an opening at least one end, and the free end of at least one of the spirals is adapted to extend through the opening to form a connection.

11. The device of claim **9**, wherein the central connector and the second end have a snap-fit connection.

12. The device of claim **1**, wherein the first spiral spirals outwardly from the central connector and extends from an outermost point radially back to the central connector where the radial portion is connected to the central connector.

13. The device of claim **12**, wherein the radial portion is detachably connected to the central connector.

14. The device of claim **12**, wherein the radial portion is non-detachably connected to the central connector.

15. A device adapted to be disposed in a patent foramen ovale tunnel and comprising first and second separate spirals and a connecting member together connected to the spirals with respective first and second joints, wherein each spiral has one end at an outer edge connected to one of the first and second joints, and a second end connectible to the respective first or second joint, the spirals forming closed loops when the second end is connected.

16. The device of claim **15**, wherein the spirals spiral outwardly from the first and second joints and have a radial portion extending inwardly from an outermost part of a spiral.

17. The device of claim **15**, wherein the connecting member includes two wires extending between the first and second joints.

18. The device of claim **15**, further comprising a membrane attached to the connecting member for promoting tissue growth.

19. The device of claim **15**, wherein the first and second joints have an opening for the second end to extend through.

20. The device of claim **15**, wherein the first and second joints have snap fit connectors for connection to the respective second ends.

21. A method comprising introducing into a patent foramen ovale (PFO) the device of claim **1**.

22. The method of claim **21**, wherein the introducing includes first providing a wire into the body, and then providing the device over the wire.

23. The method of claim **22**, wherein the method includes loading the device into a sheath, providing a catheter to limit movement of the device in the proximal direction, and providing the catheter, device, and sheath to the region near the PFO.

24. The method of claim **23**, further comprising extending the sheath and device through a PFO tunnel to a left atrium, limiting movement of the device in the proximal direction, and withdrawing the sheath in the proximal direction to release the second spiral on the left atrium side of the PFO.

25. The method of claim **24**, further comprising further withdrawing the sheath in the proximal direction.

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